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EXAMINING THE RESPONSE TO LUNG ILLNESS AND RISING YOUTH ELECTRONIC CIGARETTE USE

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED SIXTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING THE RESPONSE TO LUNG ILLNESSES AND RISING YOUTH ELECTRONIC CIGARETTE USE

NOVEMBER 13, 2019

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C O N T E N T S

STATEMENTS

WEDNESDAY, NOVEMBER 13, 2019

EXAMINING THE RESPONSE TO LUNG ILLNESS AND RISING YOUTH ELECTRONIC CIGARETTE USE

Wednesday, November 13, 2019

U.S. SENATE
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 10:04 a.m., in room SD–430, Dirksen Senate Office Building, Hon. Lamar Alexander, Chairman of the Committee, presiding.

Present: Senators Alexander [presiding], Enzi, Burr, Paul, Collins, Cassidy, Murkowski, Romney, Murray, Casey, Baldwin, Murphy, Kaine, Hassan, Smith, Jones, and Rosen.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. Good morning. The Committee on Health, Education, Labor, and Pensions will please come to order. I often suggest that Americans look at Washington, DC. as if you were looking at a split screen television. Today is a good example. On the one screen, you have the House of Representatives beginning public impeachment hearings into the President of the United States while on the other side you have a bipartisan group of Senators investigating a mysterious illness tied to e-cigarette use that has harmed more than 2,000 Americans. With 39 of those who have died, at a time when as many as 1 in 10, Tennessee high school students, and 1 in 4 high school students nationwide are using e-cigarettes, most of them illegally purchased.

If you walk into a convenience store to buy aspirin you assume the Food and Drug Administration has said it is safe and effective. When you pick up a package of peanut butter crackers, you assume the FDA ensured it was packaged in a clean space. That is when you go and check out and you grab an apple from a basket on the counter, you would assume FDA has established rules for how it was grown. And so when you go to buy one of these, this is an e-cigarette, you would also assume that someone says that it is okay to buy it, but you would be wrong because this is an e-cigarette and the Food and Drug Administration has not used its authorities to say whether or not they are okay to be sold.

Not a single e-cigarette or vaping product has been reviewed and cleared for sale by the Food and Drug Administration. According to data from FDA and the Centers for Disease Control and Prevention, over the last 2 years, 13.5 million Americans, including over 5 million teenagers, have used e-cigarettes with about 1.6 million

teenagers using e-cigarettes frequently. Remember, e-cigarettes are tobacco products so legally it is illegal to sell tobacco products to persons under 18. In Tennessee, about 1 in 20 adults use e-cigarettes some day or every day, and about 1 in 10 high school students used an e-cigarette in the last 30 days.

According to CDC and FDA information, as many 1 in 4 high school students are using e-cigarettes. Over the last 6 months, there have been 2,051 Americans hurt, 39 have died, including two in Tennessee, from vaping-related lung illnesses, many from vaping with THC, the derivative of marijuana that makes people high. So here is what I would like to learn today. One, what have FDA and the CDC learned about the more than 2,000 Americans who have gotten hurt from vaping. Second, 3 years after FDA said it had the authority to regulate e-cigarettes, why aren't there any rules in effect about what standards e-cigarettes and vaping products need to meet? Three, what should FDA be doing to regulate and review these products? Four, there has been a 700 percent increase in the number of teenagers vaping since 2013.

What has the FDA and CDC done about this surge of teenagers vaping? And fifth, how much of the $5.5 billion that the Center for Tobacco Products at FDA has received in user fees from the tobacco industry over the last decade has been spent on e-cigarettes and vaping? These so-called e-cigarettes, which can turn a liquid containing nicotine into a vapor, can look like a pen, or a USB flash drive that you plug into your computer, or a regular cigarette. These are some of the pictures right here. Those are the devices that can be seen.

Sometimes the liquid has a flavor, a mint or fruit flavor for example, that can be particularly appealing to younger people. To make this one work, this one here, there is a cartridge with liquid containing nicotine derived from tobacco, and it begins to operate automatically when you inhale it. In March of this year, doctors began to see patients with shortness of breath, chest pain, nausea, vomiting, and other symptoms, with no obvious cause.

The common thread was that all the patients had used e-cigarettes. On August 1, CDC, in coordination with FDA, began an investigation into this outbreak of vaping-related illnesses. While a large number of the cases involve THC, the derivative of marijuana that makes people high, Americans using e-cigarettes are inhaling something that is damaging their lungs and we need to find out what that is. Last Friday, the Centers for Disease Control announced the discovery of an additional "very strong culprit," a form of vitamin E called Vitamin E acetate. According to CDC, inhaling Vitamin E acetate could harm your lungs. I look forward to hearing more about what CDC and FDA have found. In the middle of this outbreak of vaping-related illnesses and a 700 percent increase in the number of teenagers using e-cigarettes since 2013, I am concerned that the Center for Tobacco Products has received almost $5.5 billion in user fees and that there are no rules in effect yet to regulate e-cigarettes.

This means that more than 8 million adults have used e-cigarettes, many instead of smoking, that FDA has not said are okay to be sold. FDA has not always regulated tobacco products. In 2009, ten years ago, Congress passed the Family Smoking Preven-

tion and Tobacco Control Act, giving the Center for Tobacco Products at FDA the authority to regulate tobacco products. I voted against this bill because I thought it did the right thing in the wrong way.

I was concerned that FDA was already overwhelmed with ensuring the safety of our medicines and food supply and did not need the added burden of regulating tobacco. Nevertheless, Congress disagreed, and in 2009 Congress and the President gave the FDA the job of regulating tobacco products—ten years ago. By 2011, e-cigarettes were becoming widely used products, and the National Youth Tobacco Survey reported that teenagers were beginning to use e-cigarettes as well.

Now here is—this shows the increase. So we see, that starts in 2011, 2009 was when tobacco products were regulated by the FDA, 2011 began the used survey of tobacco products. In 2016, the FDA said that e-cigarettes were a part of tobacco products, regulated in the same way. And you can see in the red line at the top, the FDA and CDC figures that suggest that as many as 1 in 4 of high school students are using e-cigarettes. So it wasn't until 2016, 5 years after e-cigarettes were becoming widely used, that FDA announced it would begin regulating e-cigarettes as tobacco products. As a result, it has been illegal under Federal law to sell e-cigarettes to anyone under 18 since 2016.

Despite the fact that FDA has been in charge of tobacco since 2009, has been tracking youth use of e-cigarettes since 2011, declared it would begin to regulate e-cigarettes in 2016, there are no rules in effect for manufacturers of those vaping products. It was just earlier this year that FDA took the first step, the Agency proposed a rule in April and a second in September, to give manufacturers direction on what information FDA would need to review and authorize e-cigarettes. FDA needs to make these rules final so that manufacturers have clear standards and so consumers know that the e-cigarettes they are buying have met certain qualifications. The only reason e-cigarettes are allowed to be sold at the convenience store is because FDA has decided to allow them to be sold while the Agency sets those standards.

In addition, because it is already illegal to sell e-cigarettes to those under 18. FDA has the authority to prevent online shops and stores from selling to teenagers. But parents, teachers, and principals are overwhelmed by the number of teenagers vaping—more than 5 million teenagers reported using an e-cigarette in the last 30 days, according to a recent National Youth Tobacco Survey.

In just one year, 2013 to 2014, youth use of e-cigarettes tripled. Since 2014, the number of high school students using these products has more than doubled. I know the administration has been concerned about the number teenagers using e-cigarettes and is working on a proposal to address flavored e-cigarettes. A step Congress could take would be to pass Senators McConnell and Kaine's provision in our Lower Health Care Costs Act, which raises the minimum age for purchasing any tobacco product, including e-cigarettes, from 18 to 21.

In conclusion, this is the reality, 13.5 million Americans, including more than 5 million teenagers, have reported using e-cigarettes, with 1.6 million teenagers vaping regularly, and these prod-

ucts have not yet met any FDA rules or standards. And over the last 6 months, more than 2,000 Americans have gotten sick, and 39 have died, from lung illness related to vaping. This is an unacceptable situation that demands our attention and I look forward to hearing from our witnesses today.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Well, thank you, Mr. Chairman, for having this hearing and thank you to our witnesses for joining us today. Right now, families across the country are worried about the epidemic of lung injuries that are associated with e-cigarettes or vaping products that, as the Chairman has said, has struck over 2,000 people, including 14 in Washington State, and claimed 39 lives. My heart goes out to all the victims and their families.

I know all of my colleagues agree this is an urgent issue, and we are all very interested in what our witnesses today have to tell us about this crisis, and what steps we can take to stop it in its tracks and prevent similar outbreaks in the future. And beyond this new illness, families across the country are also deeply concerned about the continuing uptick in youth e-cigarette use. Again as the Chairman said, the latest data is showing us that 1 in 4 high school students and 1 in 10 middle school students are using e-cigarettes. That is a really alarming increase and is fueled by companies' efforts to appeal to kids, threatens decades of work, and puts a generation of children at risk of nicotine addiction.

For years, popular e-cigarette brands, like Juul, the brand we know most kids use, have appealed to kids through flavors like mint, menthol, and creme brulee and youth-savvy advertising, like campaigns with influencer personalities, among other tactics. While the communities across the country are treating nicotine addiction among kids like a public health crisis, e-cigarette companies have been treating it like a business plan. In fact, Juul reportedly not only knew how addictive and appealing its product would be for kids but used the addictiveness to market the product to retailers. One Juul pod can have as much nicotine as a pack of cigarettes and many kids don't even realize it. This crisis is spiraling out of control and it requires swift, bold action.

For years, President Trump and his team have shown little interest in taking on the tobacco industry behind this epidemic and fighting for our children. His advisor Kellyanne Conway, recently and wrongly said the FDA has no jurisdiction over vaping and vape shops. Another of President Trump's leading voices on health care policy said he doesn't believe the FDA should even be regulating tobacco products and that the FDA's regulation of tobacco is, believe it or not, a "huge waste of time." That is not merely alarming, it is dead wrong. But it is not just the Trump administration's words that should make families skeptical, it is putting our children's best interests ahead of tobacco companies' products and profits, it is the administration's actions.

In 2017, the Trump administration delayed FDA oversight of existing e-cigarette products by four years. The decision, which former FDA Commissioner Gottlieb has since admitted was a mistake and a court has since ruled was unlawful, was a victory for

companies like Juul, which were able to continue targeting our Nation's youth and selling flavored products that appealed to kids. In the years since the Trump administration decided to hit the snooze button on making sure e-cigarettes meet even the most basic standards, youth tobacco use has skyrocketed, driven by e-cigarette use which has more than doubled among high school students since 2017, and more than tripled among middle school students.

While the Trump administration's decision to delay oversight of products already on the market has allowed this crisis to grow, its lackluster enforcement against new products coming to market illegally, has allowed it to fester, creating a wild west of vape products that are unregulated, and that can be incredibly dangerous in all sorts of ways, something the current epidemic of vaping-related illness has made all too clear. Between the crisis of rising youth tobacco use, and the alarming outbreak of vaping related illnesses, families are counting on us to act quickly and keep them safe.

Washington State is one of several states that has already taken action by passing an emergency rule to ban flavored e-cigarettes and raising the purchasing age for tobacco to 21. This Committee has also advanced legislation to raise the purchasing age to 21 nationally, but while we push for that step, there is still much more that needs to be done, including immediately clearing the market of all flavored e-cigarettes that have not undergone FDA review. Unfortunately, despite President Trump's recent promise to clear the market of non-tobacco flavored e-cigarettes nationally, a promise that, for the first time, seemed to indicate this administration was taking the youth vaping epidemic seriously, reporting now suggests he may be walking away from that proposal altogether, or planning to bow to tobacco industry pressure with a watered-down policy that could carve out vape shops, and leave menthol, a huge category of incredibly popular e-cigarette flavors, unaddressed. That would be a massive loophole, and absolutely unacceptable.

In fact, new data released just last week showed us that youth use of mint and menthol e-cigarettes dramatically increased over the last year alone. We need swift, bold action, not delays and half-steps. And that doesn't just go for e-cigarettes, but also for cigars, including kid-appealing flavored cigars, cigarettes, including menthol cigarettes, and other tobacco products. We need to continue investing in public health programs and preventive measures through CDC. And we need real progress on reducing the levels of nicotine in cigarettes, another policy the Trump administration promised but I am going to keep pushing for. And I am absolutely going to be pushing President Trump's new nominee to lead the FDA about his plans to fight tobacco use as well.

Because our communities, our kids, cannot wait for the Trump administration to get its act together. Back in my home State of Washington, the La Conner school district recently filed a lawsuit against Juul for its role in the epidemic of youth tobacco use. Meanwhile, students at Jackson high school are encouraging their peers to take a pledge against vaping. And earlier this year, Madison, a young student from Ridgefield High School, testified in front of the state legislature about her own experience with e-cigarette addiction, and encouraged our lawmakers to take action.

Leaders and advocates across the country are doing everything they can to respond to this crisis, and they deserve to know that we are doing everything we can too. That is why I am going to keep pushing for action on e-cigarettes and vaping, and I know there are Members on both sides of the aisle that want us to do more on this as well. So I hope we can take what we learn from this hearing and use it to continue working together, in a bipartisan way, on common sense steps to keep our kids, and our communities, safe.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murray. We have good attendance today. I am glad to see that. We have a vote at 11 a.m., but we will continue the hearing right through the votes and we will alternate chairing the hearing so every Senator will have a chance to ask questions that they would like to ask. We appreciate our witnesses coming today and thank you for your willingness to serve our country in such important roles. We would ask you each to summarize your comments in about five minutes, which will allow more time for back and forth between you and Senators.

First, we will hear from Mitch Zeller. Mr. Zeller is Director of the U.S. Food and Drug Administration Center for Tobacco Products. In this role, he leads FDA's effort to reduce tobacco related death and disease through research and regulation. He has worked on FDA related issues for more than 30 years, joined the Agency in 1993, when he was the first Associate Commissioner and Director of the Office of Tobacco programs. He left FDA in 2000 and returned to lead the Center for Tobacco Products in 2013. He is a graduate of Dartmouth and has a J.D. from American University.

Our second witness is Dr. Anne Schuchat. She is the Principal Deputy Director for the Center for Disease, Control and Prevention. She has held a variety of leadership roles there, including Acting Director, Director of the National Center for Immunization and Respiratory Diseases, and Chief of the Respiratory Diseases branch. Since joining CDC as an Epidemic Intelligence Service Officer in 1998, she has played key roles in its public health emergency responses, including the 2009 pandemic influenza response, the 2003 SARS outbreak, and the 2001 Anthrax attack.

In 2008, she retired from the Commission Corps of the United States Public Health Service at the rank of Rear Admiral completing 30 years of service. She is a graduate of Swarthmore and received her M.D. from Dartmouth. We welcome both witnesses. Mr. Zeller let us begin with you.

STATEMENT OF MITCH ZELLER, DIRECTOR, CENTER FOR TOBACCO PRODUCTS, U.S. FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MD

Mr. ZELLER. Good morning, Chairman Alexander, Ranking Member Murray, Members of the Committee, and thank you for the opportunity to be here today. I want to assure the Committee of the seriousness with which FDA takes its responsibilities on the public health issues that the Chairman and Ranking Member have already discussed.

I am here today representing hundreds of staff at FDA who are working tirelessly to both prevent kids from starting to use any tobacco product, including e-cigarettes, and in collaboration with our

colleagues at CDC, to get to the bottom through an investigation of what is causing these lung injuries. I will begin by discussing e-cigarette regulation and then provide an update on the lung injury investigation.

FDA's initial efforts to regulate e-cigarettes began more than a decade ago, long before the rise in youth use and the multi-state lung injury outbreak. Between 2008 and 2010, FDA attempted to regulate e-cigarettes as unapproved drug device combination products. Our actions were challenged and ultimately overturned in court. In the decade since the Tobacco Control Act was passed, FDA has established a science-based approach to the regulation of tobacco products, vigorously enforced our authorities to target manufacturers and retailers that violate the law and designed innovative campaigns to educate youth on the dangers of tobacco use.

The Tobacco Control Act provided FDA the authority to regulate e-cigarettes as tobacco products. Publication of the final deeming rule brought e-cigarettes under FDA's regulatory authority on August 8th, 2016. Let me highlight some of the actions that we have taken to address the epidemic of kids' use of e-cigarettes. We have issued more than 10,000 warning letters and filed more than 1,500 civil money penalty complaints against online and brick and mortar retailers for the illegal sale of e-cigarettes to kids. We have issued warning letters to six companies, notifying them of the need to remove more than 140 illegally marketed products from the market. We have issued warning letters that have resulted in the removal of dozens of e-liquid products that resemble kid friendly foods, like juice boxes, cereal, and candy.

We have issued a warning letter to Juul labs for marketing unauthorized modified risk tobacco products. Last year, we launched the Real Cost Youth E-Cigarette Prevention Campaign, which features hard-hitting advertising on TV and on digital and social media sites popular among teens, as well as getting posters with e-cigarette prevention messages placed in every single public and private high school in the country. Finally, we joined forces with scholastic to develop educational resources that have been distributed to more than 1 million middle school and high school educators. Despite these efforts, the youth vaping epidemic continues to grow and we need to do more. As the Committee considers the issues related to e-cigarette use, it is important to remember that no e-cigarette in the United States is on the market legally because none have obtained a marketing authorization from FDA.

When we announced changes to our enforcement discretion policy in August 2017, at the time nationally representative data suggested that youth use of e-cigarettes had declined. However, as the Chairman and the Ranking Member pointed out and as we all know, last year with the release of the National Youth Tobacco Survey or NYTS, the results showed that between 2017 and 2018 current e-cigarette use among high school students increased by 78 percent and by 48 percent among middle school students. Last week, we released the 2019 NYTS data showing that current e-cigarette had risen to 27.5 percent among high school students and 10.5 percent among middle school students. As in previous years, the 2019 NYTS shows a disturbing rate of youth use of flavored e-cigarettes.

Among current exclusive e-cigarette users, nearly three-quarters of those in high school and more than a half of those in middle school used flavored e-cigarettes. We are committed to doing everything that we can to prevent kids from using tobacco products and we will continue to develop a policy approach that aligns with that concern. Let me now turn to the lung injuries. FDA is deeply concerned by reports of injuries and deaths linked to use of vaping products and investigating this crisis is a top priority. On September 6th we activated an Incident Management Group or IMG to coordinate the Agency's investigation. The IMG is comprised of subject matter experts from across FDA dedicated to better understanding the relationship between any specific products or substances and the reported cases.

Our labs have received over 1,000 samples from 25 states including 850 samples connected to patients. Samples associated with 69 of these patients have been examined. 80 percent of the 69 linked cases involve THC products. 75 percent of the linked cases involving THC include products with vitamin E acetate as a diluent. I want to thank the Committee for the opportunity to appear today.

We appreciate the Committee's support for the Agency and for our vital public health mission. And I am happy to answer any questions that you have. Thank you.

[The prepared statement of Mr. Zeller follows:]

PREPARED STATEMENT OF MITCH ZELLER

Introduction

Good morning, Chairman Alexander, Ranking Member Murray, and Members of the Committee. Thank you for the opportunity to be here today to discuss the Food and Drug Administration's (FDA or the Agency) regulation of electronic nicotine delivery systems, or ENDS, which include e-cigarettes, and the Agency's role in the ongoing investigation into vaping product use associated lung injury. I am Mitch Zeller, Director of the U.S. Food and Drug Administration's Center for Tobacco Products.

I appreciate the opportunity to be here today to provide an update on FDA's regulation of ENDS, and to provide an update on FDA's efforts to investigate the illnesses associated with the use of vaping products.

In my testimony I will begin with some background on FDA's tobacco product regulatory authorities. I will then address the history of our regulation of e-cigarettes and where we find ourselves today, confronting the epidemic levels of youth use of e-cigarettes. Finally, I will discuss FDA's role in the Federal and state investigation of the cases of lung injury.

Background

Let me start with some background on our tobacco regulatory authorities.

Tobacco use is the single largest preventable cause of disease and death in the United States. Each year, more than 480,000 people in the United States die prematurely from diseases caused by cigarette smoking and exposure to tobacco smoke. In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize FDA to oversee the manufacture, marketing, distribution, and sale of tobacco products and protect the public from the harmful effects of tobacco product use. This authority gave FDA comprehensive tools to protect the public from the harmful effects of tobacco use through science-based tobacco product regulation.

Through premarket review, FDA evaluates new tobacco products based on applicable public health standards that include, for example, a consideration of the risks and benefits of the tobacco product to the population as a whole, including users and non-users. Similarly, when developing certain regulations such as product standards or restrictions on tobacco sales and advertising, the law requires FDA to

apply a public health approach that considers the effect of the regulatory action on the population as a whole, not just on individual users, taking into account the likelihood of initiation and cessation of tobacco use.

Under the statute, FDA had immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Tobacco Control Act also authorized FDA to "deem" other "tobacco products" (which include "any product made or derived from tobacco that is intended for human consumption" that is not a drug, device, or combination product under the FD&C Act, "including any component, part, or accessory" of that product) to be subject to the Agency's regulatory authority in Chapter IX of the FD&C Act.

It's important to note FDA's initial efforts to regulate e-cigarettes more than a decade ago, long before the rise in youth use and the multi-state lung injury outbreak. Between 2008 and 2010, FDA attempted to regulate e-cigarettes as unapproved drug/device combination products. FDA's action was challenged, and ultimately the U.S. Court of Appeals for the D.C. Circuit ruled that while FDA could choose to regulate e-cigarettes and other products "made or derived from tobacco" under its new tobacco authorities, it could not regulate these products under FDA's drug and device authority unless they were marketed for therapeutic purposes. *Sottera, Inc. v. Food and Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010).

Publication of the final deeming rule brought e-cigarettes under FDA's regulatory authority for tobacco products. That rule was issued on May 10, 2016, deeming additional products that meet the statutory definition of a "tobacco product," except for accessories of such products, to be subject to FDA's regulatory authority. Deemed products include ENDS, cigars, pipe tobacco, nicotine gels, waterpipe (or hookah) tobacco, and any future tobacco products. The deeming rule, and FDA's regulation of these products, took effect on August 8, 2016.

Regulatory Requirements for ENDS Products

When the deeming rule took effect in August 2016, many of the regulatory and legal requirements that had been in place for manufacturers of cigarettes, smokeless tobacco, cigarette tobacco, and roll-your-own tobacco since 2009, as well as several new requirements specific to deemed products, became applicable to makers of e-cigarettes and other ENDS products. These include:

- Registering domestic establishments and submitting lists of products manufactured at those establishments, including all labeling and representative samples of advertisements;
- Submitting tobacco health documents;
- Submitting ingredient listings;
- Marketing new tobacco products only after FDA review; and
- Marketing products with direct or implied claims of reduced risk only if FDA confirms that scientific evidence supports the claim and determines that providing a marketing authorization for the product will, among other things, benefit the health of the population as a whole.

In addition, under the deeming rule, the following regulatory provisions also apply to deemed tobacco products, including ENDS products:

- Minimum age restriction (18 years or older) and identification requirements to prevent sales to underage youth;
- Requirements to bear certain health warnings on packages and advertisements (including certain ENDS components, such as e-liquids) such as, "WARNING: This product contains nicotine. Nicotine is an addictive chemical." and
- Prohibition of vending machine sales, unless in a facility that never admits youth.

To provide time for industry to come into compliance with some of the new regulatory requirements triggered by the final deeming rule, FDA announced an enforcement policy with staggered timeframes. Some of the requirements, such as the Federal minimum age of purchase (18 years or older), were enforced immediately when the deeming rule took effect on August 8, 2016, while, through an exercise of enforcement discretion, FDA temporarily deferred enforcement of other provisions such as premarket review of "new" tobacco products.

Premarket Review of ENDS

All deemed products, including ENDS, became subject to the premarket authorization requirements in the Tobacco Control Act on August 8, 2016. All "new tobacco products" are required to obtain authorization from FDA before they can be legally marketed. Pursuant to the Tobacco Control Act, a "new tobacco product" is one that was not commercially marketed as of February 15, 2007, or that was modified after February 15, 2007.

FDA's initial compliance policy for premarket review stated that the Agency did not intend to enforce the requirements of premarket review against manufacturers of newly regulated new tobacco products that were on the market as of August 8, 2016, as long as they submitted marketing applications and received authorization within specific timeframes. As a result, FDA anticipated that many ENDS products would remain on the market without premarket authorization for up to three years.

In July 2017, FDA announced a new comprehensive plan for tobacco and nicotine regulation that would serve as a multi-year roadmap in an effort to significantly reduce tobacco-related disease and death. The comprehensive plan was announced in part to afford the Agency time to explore other meaningful measures, beyond premarket review, to make combustible tobacco products less toxic, less appealing, and less addictive. One aspect of the plan involved striking a balance between conducting reasonable oversight through regulation and encouraging development of innovative tobacco products that may be less harmful than cigarettes. The Agency announced that it planned to issue an updated compliance policy to defer some enforcement timelines described in the preamble to the final deeming rule.

Since that announcement, FDA has been hard at work on rules, guidances, and other communications that will help manufacturers develop higher quality applications, including the issuance of the following:

- Substantial Equivalence pathway proposed rule
- Premarket Tobacco Application for ENDS final guidance
- Premarket Tobacco Application proposed rule
- Vape shops final guidance
- Regular meetings with manufacturers to provide guidance on premarket authorization processes
- Regular meetings with retailers on e-cigarette policies of particular importance for retailers such as efforts to prevent youth sales and the availability of free educational resources for retailers to assist them in preventing youth sales
- Draft guidance on Developing Nicotine Replacement Therapy Drug Products
- Draft guidance on Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products Guidance for Industry

The July 2017 announcement led to publication of the August 2017 Compliance Policy, which was later the subject of litigation. In May 2019, a U.S. District Court in Maryland vacated FDA's August 2017 Compliance Policy. In July 2019, the court issued a further order directing FDA to require that applications for deemed "new tobacco products" such as e-cigarettes, cigars, pipe tobacco, and hookah tobacco, that were on the market as of August 8, 2016, be filed with FDA no later than May 12, 2020. The court order also provided for a one-year period during which products with timely filed applications might remain on the market pending FDA review, but subsequently clarified that its order does not restrict the Agency's authority to enforce the premarket review provisions against deemed products prior to May 12, 2020, or during the one-year review period.

As the Committee considers the issues related to e-cigarette use today, it is important to remember that no ENDS product in the United States is on the market legally. To be legally marketed as a tobacco product, the product would need to obtain premarket authorization from the Agency. The product would undergo FDA scientific review, and (assuming that the product is being reviewed through the Premarket Tobacco Application pathway) the Agency would have to find that the product meets the applicable statutory standard for marketing—for example, that the product is appropriate for the protection of the public health. Alternatively, an ENDS product that is intended for therapeutic purposes (e.g., smoking cessation) would need to be reviewed and approved under FDA's drug authorities to be legally marketed as a drug. Currently, there is no FDA-authorized or FDA-approved ENDS product on the market.

FDA's Aggressive Actions to Address the Youth Epidemic of ENDS Product Use

At the time FDA issued the August 2017 Compliance Policy to modify the enforcement discretion policies regarding premarket authorization, nationally representative data suggested that youth use of e-cigarettes had declined.[1] While no level of youth use is acceptable, FDA took this directional data into consideration, along with the potential benefits some of these products might provide to some addicted individual adult smokers seeking to make a complete transition away from combustible cigarettes.

The Agency was engaged in a public health balancing act. Given the then-existing evidence suggesting a decline in youth use, and with the potential for FDA to pursue other bold measures, in part by reducing the addictiveness of combustible cigarettes while temporarily delaying the likely immediate market exit of newly deemed tobacco products that could be potentially less harmful to individual users, FDA determined that the balancing of public health considerations argued in favor of a different comprehensive approach to nicotine and tobacco regulation.

However, only a year after we announced the 2017 comprehensive plan, the National Youth Tobacco Survey (NYTS) in 2018 showed a new and significant increase in youth use of e-cigarettes. FDA collaborates with CDC to administer the survey to middle and high school students each year. The survey provides important data that allow us to understand current youth tobacco product use in a larger historical context.

Between 2017 and 2018, current (past 30-day) e-cigarette use among high school students increased 78 percent, from 11.7 percent to 20.8 percent.[2] Current e-cigarette use among middle school students increased by 48 percent over the same time period, from 3.3 percent to 4.9 percent.[3] Moreover, evidence demonstrated that youth are especially attracted to flavored ENDS products. Data from the 2018 NYTS showed that, in just one year, current use of flavored e-cigarettes increased substantially among high school students who were current e-cigarette users, from 60.9 percent in 2017 to 67.8 percent in 2018.[4] In addition, the proportion of current e-cigarette users in high school who reported use on 20 or more days of the past 30 days increased from 20.0 percent in 2017 to 27.7 percent in 2018.

FDA and CDC recently published 2019 NYTS data in the *Journal of the American Medical Association* (JAMA).[5] Unfortunately, the data show that current e-cigarette use among youth has continued at its alarming increase, with 27.5 percent of high school students and 10.5 percent of middle school students reporting current use of e-cigarettes. The data also showed that more than five million U.S. middle and high school students are current e-cigarette users. Further, most of those middle and high school students who exclusively use e-cigarettes are using flavored products. And the survey shows that 34.2 percent of current high school e-cigarette users in 2019 are using the product frequently (use on 20 or more days in the last 30 days). In total, 1.6 million middle school and high school current e-cigarette users were frequent users, with nearly one million using e-cigarettes daily.

As in previous years, the 2019 NYTS shows a disturbing rate of youth use of non-tobacco flavored e-cigarettes. In particular, the data show that among current exclusive e-cigarette users, nearly three quarters of those in high school and more than half of those in middle school used flavored e-cigarettes. The most commonly reported flavors were fruit, menthol or mint (evaluated as a single category), and candy, desserts, or other sweets.[6] Importantly, findings from another study, the 2019 Monitoring the Future (MTF) survey—also published in JAMA on November 5, 2019—give us a more granular picture of flavor preferences as they relate to this public health balancing act. These findings indicate that youth preference for menthol- and tobacco-flavored products is much *lower* than that for mint- and fruit-

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[1] Jamal A, Gentzke A, Hu SS, et al. Tobacco Use Among Middle and High School Students—United States, 2011–2016. MMWR Morb Mortal Wkly Rep 2017;66:597–603. *https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a1.htm?s_*cid=mm6623a1_w. The NYTS defines e-cigarettes as "battery-powered devices that provide nicotine and other additives to the user in the form of an aerosol."

[2] Id.

[3] Id.

[4] Cullen, K.A., B.K. Ambrose, A.S. Gentzke, et al., "Notes from the Field: Increase in e-cigarette use and any tobacco product use among middle and high school students—United States, 2011–2018," *Morbidity and Mortality Weekly*, 67(45);1276–1277 (2018).

[5] *https://jamanetwork.com/journals/jama/fullarticle/2755265*.

[6] Cullen KA, Gentzke AS, Sawdey MD, et al., "E-Cigarette Use Among Youth in the United States, 2019," JAMA.

flavored products. This recent analysis was limited to youth who indicated they had specifically used the JUUL brand.

We are committed to doing everything we can to prevent kids from using tobacco products and will continue to develop a policy approach that aligns with that concern. Additionally, we are taking a number of other actions to help address the youth use epidemic:

- FDA has been holding retailers and manufacturers accountable for marketing and sales practices that have led to increased youth accessibility and appeal of e-cigarettes. For example, since the effective date of the Deeming Rule in August 2016, FDA has issued more than 10,000 warning letters to, and filed more than 1,500 civil money penalty complaints against, retailers, both online and in brick-and-mortar retail stores, for sales of ENDS and their components to youth.
- FDA has sent letters to over 100 companies seeking information on over 130 brands, including ENDS products, to determine whether those products were not marketed as of August 8, 2016, and therefore not subject to any previous FDA compliance policy. To date, FDA has issued warning letters to six ENDS companies notifying them of the need to remove a combined total of more than 140 products from the market.
- The Agency has issued warning letters, many in collaboration with the Federal Trade Commission (FTC), that resulted in the removal of dozens of e-liquid products resembling kid-friendly foods, such as juice boxes, cereal, and candy.
- On September 9, 2019, FDA issued a warning letter[7] to JUUL Labs Inc. for marketing unauthorized modified risk tobacco products by engaging in labeling, advertising, and/or other activities directed to consumers, including a presentation given to youth at a school, by marketing it for reduced risk or harm from using the product compared to cigarette smoking. Concurrently, the Agency issued a second letter expressing its concern and requesting additional information about several issues raised by Congress regarding JUUL's outreach and marketing practices, including those targeted at students, tribes, health insurers and employers.
- FDA has also continued to invest in campaigns to educate youth about the dangers of e-cigarette use. Last year, FDA launched "The Real Cost" Youth E-Cigarette Prevention Campaign[8]—a comprehensive effort targeting nearly 10.7 million youth, aged 12–17, who have used e-cigarettes or are open to trying them. The campaign features hard-hitting advertising on TV, digital and social media sites popular among teens, as well as posters with e-cigarette prevention messages in high schools across the Nation.
- FDA joined forces with Scholastic to develop educational resources for middle and high school teachers and administrators. These materials have been distributed to more than 1 million middle and high school educators. Our work with Scholastic continues and more resources will be made available in Spring 2020.
- The Agency also developed posters and resources for doctors, youth groups, religious institutions, state and local public health agencies, and others on the dangers of youth e-cigarette use and has worked to advance discussion and understanding around how to help those kids who are already addicted to e-cigarettes quit.

We will continue to take vigorous actions aimed at ensuring e-cigarettes and other tobacco products are not being marketed or sold to kids. In addition, we will continue to expand our public education efforts to get the word out to youth about the harms of e-cigarettes.

Investing in Research to Learn More About the Health Impacts of ENDS Products

FDA is funding several research projects assessing the health impact of e-cigarettes, including the FDA and NIH Population Assessment of Tobacco and Health

[7] The warning letter is available at: *https://www.fda.gov/news-events/press-announcements/fda-warns-juul-labs-marketing-unauthorized-modified-risk-tobacco-products-including-outreach-youth*.

[8] More information is available at: *https://www.fda.gov/tobacco-products/real-cost-campaign*.

(PATH) Study. The PATH Study is a national, longitudinal cohort study of almost 46,000 youth and adults in the United States that collected its first wave of data in 2013 and is following study participants over time to learn how and why people start using tobacco products, quit using them, and start using them again after they have quit, as well as how different tobacco products affect health (such as cardiovascular and respiratory health) over time. The PATH Study is tracking potential behavioral and health impacts, including collecting biospecimens to analyze for biomarkers of exposure and harm.[9]

In 2016, FDA awarded a contract to National Academy of Sciences, Engineering and Medicine (NASEM) to "conduct an in-depth evaluation of the available evidence of health effects from electronic nicotine delivery systems (ENDS) and make recommendations for future federally funded research." This work included convening a multi-disciplinary committee of 13 members that met several times and holding an open meeting to obtain input from a wide range of stakeholders. The committee's methodology included: a comprehensive literature search and review; a quality assessment and evidence synthesis to assess causality for health effects; and an application of a framework for levels of evidence. Over 800 peer-reviewed scientific studies were evaluated and the consensus report, "Public Health Consequences of E-Cigarettes," was released by NASEM in January 2018.[10] Among the conclusions in the NASEM report is that teens who experiment with an e-cigarette are more likely to try conventional cigarettes compared to teens who never used an e-cigarette.

As noted in the NASEM report, assessing the long-term health effects of e-cigarettes is challenging given the range of devices and constituents. For example, products can vary widely in terms of device type, mechanism, ingredients and the characteristics of aerosol generation. Variables of ENDS that could affect health impact include factors such as: exposure to metals (including heavy metals), heating capacity, voltage, e-liquid substrates, nicotine concentration, flavors and flavoring ingredients, and use of other ingredients or contaminants with unknown inhalation effects. A specific ENDS product's health impact is also likely to be significantly affected by user behaviors (and we know that many ENDS users also use other tobacco products in addition to e-cigarettes, known as dual use or poly use). Assessing the short-term health effects is also challenging for these same reasons. To help understand the individual and population impact of ENDS, FDA is currently funding more than 115 studies assessing the short- and long-term health effects of e-cigarettes including nicotine dependence, cardiovascular and pulmonary toxicity, potential carcinogenesis, effects of maternal use during pregnancy, and effects in the oral cavity.[11]

Investigation of Severe Respiratory Injury Associated with Vaping Products

FDA is also deeply concerned by the recent outbreak of severe respiratory lung injuries and reported deaths that are linked to use of vaping products. Investigating this crisis is a top priority for FDA, and the Agency is working very closely with CDC and state officials. The Agency is committed to taking appropriate actions to protect the public as the facts emerge. FDA is not pursuing any actions associated with personal use of any vaping products; our interest is in the supply chain. Every day we are gathering more information, and every day we seek to use that information to better understand the relationship between any specific products or substances and the reported illnesses. To date, most patients have reported a history of using vaping products containing tetrahydrocannabinol (THC). Many patients have reported using products containing THC and products containing nicotine. Some have reported the use of e-cigarette products containing only nicotine. We are following all potential leads and are doing all we can to move this complex investigation forward.

In recent months, this outbreak has possibly sickened, by the most recent CDC data, 2,051 people from 49 states, the District of Columbia, and one U.S. Territory. Sadly, 39 deaths have been confirmed in 24 states and the District of Columbia. These illnesses do not appear to be due to infectious diseases, but rather appear to be associated with a chemical exposure from vaping products. Patients generally report a gradual start of symptoms including breathing difficulty, gastrointestinal symptoms, and/or chest pain before hospitalization. Many patients have reported re-

[9] More information on the PATH Study can be found at *https://www.fda.gov/tobacco-products/research/fda-and-nih-study-population-assessment-tobacco-and-health*.

[10] More information can be found at *http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx*.

[11] More information can be found on the FDA website at *https://www.fda.gov/tobacco-products/research/ctp-supported-tobacco-regulatory-research-projects*.

cent use of vaping products containing THC. Although these cases seem similar, it is not clear if they have a common cause, or if they involve different diseases with similar presentations. The investigation has not identified any specific product or substance that is linked to all cases.

On September 6, 2019, FDA activated an Incident Management Group (IMG) to coordinate FDA's activities for the investigation into these reports. The IMG is comprised of subject matter experts from numerous FDA centers and offices, such as clinicians, toxicologists, pharmacologists, epidemiologists, chemists, engineers, consumer safety and criminal investigators, and computational scientists. FDA is focused on better understanding whether there is a relationship between any specific products or substances and the reported cases. It is important to stress that identifying any compounds present in the samples is but one piece of the puzzle and will not necessarily answer questions about causality, which makes our ongoing work critical.

FDA's work includes collecting critical details about the products or substances involved, where they were purchased and how they were being used and analyzing product samples. To date, FDA laboratories have received over 1,000 samples from 25 states for this investigation with roughly 850 of these samples connected to patients. Overall, 595 of the samples collected from patients have undergone some level of testing. The Agency is also working to link samples with specific patients, directly linking 509 samples to 69 patients. Eighty percent of these include links to THC products and of these 75 percent of cases included products with vitamin E acetate as a diluent. Connecting the products and how they were used to specific patients is critically important to our investigation to determine, to the extent possible, the cause or causes of these injuries.

FDA continues reaching out directly to the states that have submitted samples and is providing them high-level aggregate data in the form of status reports on preliminary analytical findings. Additionally, as the investigation continues to evolve, FDA and CDC are ensuring that information is shared seamlessly between the two agencies. FDA has assigned staff to CDC's Emergency Operations Center. Likewise, CDC has assigned staff to our IMG to facilitate collaboration. We continue to work closely on sample collection and joint testing plans for aerosol and e-liquid. The agencies also continue to share epidemiologic and product testing data to aid in linking of case patients to product testing results.

Importantly, last week CDC reported on the first analysis of human lung fluid in 29 samples from individuals in 10 states. Vitamin E acetate was found in all 29 samples. THC was found in three samples from individuals who reported they only used a nicotine-containing vaping product. More work needs to be done to get to the bottom of what substance or substances is causing these illnesses and deaths, but these findings will help us get closer to the answers we and CDC are seeking.

We are working to communicate with the public when we have information to share in a frequent and transparent way. FDA has warned consumers to avoid buying vaping products of any kind "on the street" and to refrain from vaping THC or modifying/adding any substances to products purchased in stores. FDA also encourages the public to submit detailed reports of any unexpected tobacco- or vaping-related product issues to FDA via the online Safety Reporting Portal, which can be found on our website (or at *www.safetyreporting.hhs.gov*).

Conclusion

Thank you for the opportunity to testify today about FDA's tobacco product regulatory work and our efforts to investigate vaping product use associated lung injury. FDA is committed to the evolving investigation and to protecting and improving the public health.

I am happy to answer any questions you may have.

The CHAIRMAN. Thank you, Mr. Zeller. Dr. Schuchat, welcome.

STATEMENT OF ANNE SCHUCHAT, M.D., PRINCIPAL DEPUTY DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA

Dr. SCHUCHAT. Thank you, Chairman Alexander, Ranking Member Murray, and Members of the Committee. I am happy to have the chance to provide an update on our investigation of lung injury

as well as our concerns related to the youth epidemic of e-cigarette use. I want to make four key points. First, since we first learned of these cases of lung injury on August 1st, CDC has been working 24/7 hand-in-hand with state and local public health departments as well as the FDA to get to the bottom of it. Second, our ability to do this kind of investigation relies on critical underlying public health infrastructure, including data systems that need modernization and a trained and data savvy public health workforce.

Third, CDC has made important recommendations to the public based on the investigation so far. CDC recommends that people do not use vaping products that contain THC. People should not acquire products from informal sources or the illicit market and should not modify further these products beyond what was intended by the manufacturers. While the investigation is ongoing, CDC recommends that persons consider refraining from use of all e-cigarettes or vaping products. Regardless of the investigation, e-cigarettes or vaping products should never be used by youth, young adults, or women who are pregnant. Adults who use e-cigarettes or vaping products because they have quit cigarette smoking shouldn't return to smoking cigarettes.

Fourth, we must address the broader epidemic of e-cigarette use among youth. The epidemic of lung injury is striking young people. More than half of cases are under 25 years, about 15 percent are under 18 years of age. About half of them need to be cared for in intensive care units. Fortunately, the new cases appear to be trending downward nationally, although some states remain hard hit. We continue to find that most patients report using THC containing products. Lab testing is providing important new information, but no single product, brand, substance, or additive has been identified in all of the cases at this point. It may be that there is one cause or that there are many problematic substances causing lung injury. And there may be complex root causes for this outbreak.

CDC is working vigorously with states to respond. We dispatched our disease detectives to help state and local public health and we activated our emergency operation center—our incident manager is coordinating a response. We have been holding frequent calls with public health, with clinicians, and briefings for the media in order to keep the public informed. Last Friday, we issued two key products in our morbidity and mortality weekly report. The Illinois study showed lung injury patients were significantly more likely than other people who vaped with THC to have acquired their products from friends or social sources, to use THC containing vaping products more than five times a day, and to use products that were labeled dank vapes, which is a class of largely counterfeit products of complex providence.

In a separate report, we shared the results of CDC's initial lab testing of lung fluid from patients in 10 different states. That study found vitamin E acetate but no other oily adulterants were detected in all 29 patients tested. This is the first detection of a potential toxic chemical of concern in biologic samples from patients with lung injury. We are working closely with the FDA on the trace back of products that people use and on additional laboratory testing. We have made great progress, but there have been challenges

with this response. State laws vary regarding THC and cannabis use and the investigation includes gathering information from people about potentially illicit products.

E-cigarettes or vaping products are part of a complex, multi factorial marketplace. There are many different product varieties and different substances can be used with the devices. Counterfeiting or black market products can make analysis of some brands unreliable. Public health data collection for this response relied on antiquated and fragmented systems that need modernization. The outbreak unfortunately has moved faster than our data systems and that has been a barrier to our getting quick answers. Turning quickly to the epidemic of youth use of e-cigarettes.

Youth are much more likely than adults to use e-cigarettes and flavors are a key part of that appeal. CDC has been messaging our concerns about e-cigarette use since 2013 when we got the initial data about the alarming increase from 2011 to 2012. Recently, released data from 2019 show the problem is much worse now and continues to be of great concern.

In conclusion, we are dedicated at CDC to working around the clock together with FDA and state and local health officials to stop this outbreak, address its root causes, and continue to focus on the concerning increase in youth use of e-cigarettes. I look forward to your questions.

[The prepared statement of Dr. Schuchat follows:]

PREPARED STATEMENT OF ANNE SCHUCHAT

Introduction

Good morning, Chairman Alexander, Ranking Member Murray, and Members of the Committee. I am Dr. Anne Schuchat, the Principal Deputy Director of the Centers for Disease Control and Prevention (CDC). Thank you for the opportunity to testify before the Committee regarding CDC's investigation into lung injury associated with using e-cigarettes or other vaping products, and for your continued commitment to support CDC's work to protect Americans.

On August 1, 2019, Wisconsin first alerted CDC to a cluster of pulmonary injury among young adults that began in July 2019. Since that date, CDC has been putting its scientific expertise to use across epidemiologic, laboratory, and clinical realms to address this public health crisis. CDC's response efforts are committed to: identify and define the risk factors and the sources for e-cigarettes or other vaping product use associated lung injury (EVALI); detect and track confirmed and probable cases in the United States; communicate actionable recommendations to state, local, and clinical audiences; and establish laboratory procedures to assist with public health investigations and patient care. Throughout this investigation, CDC has been partnering with colleagues at the U.S. Food and Drug Administration (FDA), state and local health departments, and other public health and clinical stakeholders to gain a comprehensive understanding of EVALI and the potential cause or causes.

As of November 5, 2019, there are 2051 confirmed and probable cases of EVALI reported by 49 states, Washington, DC, and the U.S. Virgin Islands. Most patients reported a gradual onset of difficulty breathing, shortness of breath, or chest pain before hospitalization. Some patients reported mild to moderate gastrointestinal illness. This lung condition is serious. As of November 5, 2019, 39 EVALI deaths have been confirmed in 24 states and Washington, DC, and we know that additional deaths remain under investigation by states. These tragic deaths reinforce the urgency of CDC's efforts, in close coordination with others, to identify the cause of this illness, provide recommendations to the public on how to prevent further illnesses and deaths from occurring, and to assist states to address this public health outbreak.

EVALI presents our Nation with a new public health crisis. And as the Nation's health protection agency, CDC is leveraging its cutting-edge science and expertise in public health preparedness to quickly and nimbly respond. As we do for other emergency investigations, CDC implemented an incident management structure in

August 2019 and, on September 16, 2019, activated its Emergency Operations Center. Doing so has allowed CDC to dedicate more staff and resources to this investigation. To date, approximately 300 CDC staff have been engaged in response efforts, including CDC staff who have been deployed to assist state health departments in investigating lung injuries within their jurisdictions. We also have stood up an international team that is maintaining communication with our international public health partners.

CDC is working 24/7 with FDA and state and local health officials to get at the root cause or causes of these lung injuries. CDC is in continuous discussions with states to determine ongoing and additional needs to assist in gathering data and information to monitor and identify what is leading to these lung injuries. CDC is collaborating with a wide range of partners to: facilitate sharing of information about the illnesses, and behaviors and use of e-cigarettes or other vaping products between state health departments and clinicians; analyze and link data to assist in investigations; conduct laboratory testing; coordinate national communication activities such as updates on the status of the investigation; provide public health and clinical recommendations; and provide information to states, healthcare providers, and the public.

Summary of the Epidemiology

In responding to public health emergencies, CDC's first steps are to understand what is happening, establish where it is happening, and collect as rapidly as feasible relevant data to inform our next steps. For this response in particular, we are aggregating data from our epidemiologic investigation with findings from our laboratory testing of clinical and product samples, in collaboration with FDA, to help identify who is most at risk and the specific substances or ingredients that may be causing these lung injuries.

The ongoing investigation into the cause or causes of EVALI is challenging for many reasons. First, the investigation spans almost all states and the U.S. Virgin Islands. Second, EVALI is a diagnosis of exclusion since, at present, no specific test or marker exists for its diagnosis in a patient. Third, this investigation is complicated by the diversity of the e-cigarettes or other vaping products in the marketplace. There are hundreds of products, and thousands of e-liquids used by people who use e-cigarettes or other vaping products. Fourth, people using these products may not know the ingredients in the liquid solutions, and chemicals may change when aerosolized in the e-cigarettes or other vaping products. Moreover, many of the products and substances themselves can be modified by the distributer or the user. They can be obtained from brick and mortar stores, online retailers, on the street, through the internet, or through social sources. In addition, information about the use of e-cigarettes or other vaping products relies largely on self-reporting, and interviewees may be hesitant to share information about their use of substances such as THC.

National data suggest that THC-containing products are playing an important role in this outbreak. Previously published reports from Illinois, Utah, and Wisconsin suggest that patients typically obtained their THC-containing vaping products through informal sources, such as friends or illicit in-person and online dealers, although local and regional differences in illicit THC supply and production seem to exist. CDC has regularly collected and shared information about the outbreak. On October 28, 2019, a report published in CDC's Morbidity and Mortality Weekly Report (MMWR) provided information on 867 EVALI patients with available data on substances used. Of these, 86 percent reported any use of THC-containing products in the three-months preceding symptom onset, and 64 percent reported any use of nicotine-containing products in that period. For the same period, 52 percent reported use of both THC-containing products and nicotine-containing products, 34 percent reported exclusive use of THC-containing products, and 11 percent reported exclusive use of nicotine-containing products. Two percent of patients reported no use of THC- or nicotine-containing products in that period.

This outbreak continues to disproportionately affect persons under the age of 35, highlighting the need to communicate the dangers of using e-cigarettes or other vaping products among youth and young adults, irrespective of the substances they are using in these products. In addition to the risk of severe lung injury, use of these products is also dangerous to young people because THC and nicotine both can have lasting adverse effects on brain development.

CDC's Collaboration with States

CDC staff from across the agency currently are involved in the response to coordinate activities, develop resources, and provide assistance to states, public health partners, and clinicians around the Nation. In addition to those working on this response from agency headquarters, CDC staff also have been present on the ground within different states. As of November 2, 2019, CDC has deployed a total of 22 staff to eight states to assist state health departments, at their request, in investigating these lung injuries. These staff members are in addition to the Epidemic Intelligence Service Officers and Career Epidemiology Field Officers who are already stationed in the state health departments. CDC also activated the Laboratory Response Network for Chemical Threats, which is a network of CDC, state, and local public health laboratories that provide critical laboratory testing support to the programs and providers who are responding to this outbreak.

CDC is providing scientific expertise to assist state and local public health jurisdictions. To enhance collection and analysis of data about the products, ingredients, and compounds that may be responsible for this outbreak, early on CDC worked with states and the Council of State and Territorial Epidemiologists (CSTE) to develop a uniform report form for states to use to collect data on cases, and our agency has been partnering with states to compile those data. Again collaborating with states and CSTE, CDC recently revised the national data collection instrument to provide a more streamlined means for states to collect and report their data. CDC continues to work closely with states to explore additional quantitative and qualitative studies to increase our understanding of this outbreak and product use behaviors among EVALI patients.

CDC's provision of assistance to states likewise extends to process improvements for sharing and analyzing case-associated data. For instance, CDC has implemented a data integration and management platform called DCIPHER (Data Collation and Integration for Public Health Event Response) for use in this outbreak response. This platform enables states to directly enter or import and view their data. In October 2019, CDC began piloting the use of DCIPHER with a subset of states and, as of November 2019, this platform is now available for use across all states.

CDC also is leading outreach to states in collaboration with FDA to gather information on case-associated devices and substances to help build a more comprehensive picture of these incidents. CDC is gathering reports of the types and brands of e-cigarettes or other vaping products used, the substances used, any modifications of the products, and where the products and liquids were obtained.

In October 2019, CDC expanded its laboratory testing in support of the lung injury outbreak to conduct analyses of aerosol emissions from case-associated e-cigarettes and other vaping products. Aerosol emissions testing will be conducted by CDC's Division of Laboratory Sciences, which will apply its over decade-long experience characterizing e-cigarette aerosol emissions to products associated with this outbreak. CDC's aerosol emissions testing complements FDA's testing of the case-associated e-liquids. When combined with epidemiologic and clinical laboratory data, the results found by testing case-associated product samples may provide insight into the nature of the chemical exposure or exposures contributing to EVALI.

In addition, CDC continues to offer testing of states' pathologic specimens, including lung biopsy or autopsy specimens, associated with patients, as well as testing of bronchoalveolar lavage fluid (BAL), and any blood or urine samples that are paired with BAL fluid. CDC also expanded its laboratory testing to include cannabinoids, including THC, in case-associated urine samples. CDC developed and published clear guidance documents to assist public health laboratories, healthcare providers, pathologists, and others with specimen collection, storage, and submission to CDC for testing, which is posted on our website.

Because of the variety of chemicals that are present in e-cigarette or other vaping product liquids and that may be added to these liquids, as well as the diversity of products in circulation, laboratory analyses are complex. Thus, despite CDC's enhanced laboratory capacity to assist in this outbreak, the identification of the cause or causes for EVALI may take considerable time and continuing effort.

CDC's Outreach

CDC ensures that the findings from the investigation are provided in a timely manner to the public, healthcare providers, and others. These findings are then translated into evidence-based recommendations. CDC communicates regularly with consumers, clinicians, and public health professionals through scientific publications, web products, social media, traditional media, and other channels. As of No-

vember 1, 2019, CDC has hosted seven national media telebriefings on the outbreak, joined by colleagues from the FDA and selected state health department investigators.

Throughout this investigation, CDC has been dedicated to providing guidance and targeted communications to healthcare providers. On August 16, 2019, CDC released a Clinician Outreach and Communication Activity (COCA) Clinical Action Alert describing this investigation and asking providers to report possible cases of EVALI to their state health departments. This was followed by a Health Alert Network (HAN) Health Advisory on August 30, 2019, with specific recommendations for clinicians, health officials, and the public. On September 6, 2019, CDC released additional information through several reports in the MMWR, including a summary from clinicians in North Carolina of clinical characteristics and e-cigarette or other vaping product use exposures among five cases in that state, as well as CDC guidance for public health officials, clinical providers, and the public about prevention, case identification, and reporting. On September 19, 2019, CDC conducted a follow-up COCA call with more than 2,500 clinicians in attendance, where we reviewed clinical features reported among cases, and provided CDC's recommendations for clinicians. On October 25, 2019, CDC published a factsheet for healthcare providers regarding evaluating and caring for patients with suspected EVALI.

CDC's Lung Injury website houses information specifically for healthcare providers that is updated on a continual basis. For instance, we recently included information for healthcare providers that specifically relates to influenza. As noted on our website, during flu season, CDC recommends that healthcare providers should consider flu in all patients with suspected EVALI. We also note that antivirals should be considered in accordance with established guidelines and that decisions on initiation or discontinuation of treatment should be based on specific clinical features and, when appropriate, in consultation with specialists.

Challenges

Despite all momentum gained and promising work underway across CDC, this investigation has posed a number of challenges. Public health runs on data. Protecting America's health requires reliable and up-to-date information to prevent, detect, and respond to health threats. Most public health data collection and reporting systems are antiquated and fragmented, making it challenging to assure timely, actionable information while continuing to safeguard patient privacy. This investigation is emblematic of a challenge to our agency's overall work, which requires rapid collection and analysis of public health data but is often reliant on paper-based systems and fax machines.

Timely surveillance, particularly concerning newly emerging and rapidly evolving forms of tobacco products and cannabis use other than smoking (e.g., vaping, dabbing, edibles), in the United States is nascent. Although there have been contributory efforts to improve surveillance in recent years, this outbreak, against a background of limited estimates of baseline rates of use and use behaviors related to THC use in e-cigarettes or other vaping products highlights that data collection and analysis efforts have not kept up, either technologically or with the changing landscape of e-cigarette or other vaping product use. Another inherent challenge of this investigation is the complication introduced by the reporting of potentially illicit drug use from patients. State laws vary regarding THC and cannabis use, which may make standardized and consistent data collection challenging.

Finally, the marketplace for e-cigarettes or other vaping products is wide and diverse, with a multitude of substances that can be used with the devices. This can complicate toxicology testing and the interpretation of results. Despite these challenges, CDC has taken positive steps to address the EVALI outbreak while also continuing to address the ongoing epidemic of e-cigarette use by youth in our Nation.

CDC's Efforts to Address the Epidemic of E-cigarettes

The EVALI outbreak comes at a time of epidemic-levels of e-cigarette use by young people in the United States. E-cigarettes have been the most commonly used tobacco product among youth since 2014, and their significantly increased use has erased earlier progress in reducing overall tobacco product use among youth. Notably, e-cigarette use among high school students increased by 77.8 percent from 2017 to 2018. Additionally, preliminary data from the 2019 National Youth Tobacco Survey (NYTS) demonstrate that more than a quarter of high school students reported e-cigarette use within the past 30 days.

Flavors are one of many factors associated with youth use of tobacco. Specifically, flavors can increase the appeal of tobacco products to youth, promote youth initiation of tobacco products, and result in lifelong tobacco product use. Recent data published by FDA and CDC from the NYTS found that in 2018, 67.8 percent of high school students who reported using e-cigarettes within the past 30 days used flavored e-cigarettes. These data also indicated that during 2014 to 2018, current use of flavored e-cigarettes increased among high school students.

CDC is engaged in multi-faceted efforts to prevent and reduce use of all tobacco products, including e-cigarettes, among young people. In collaboration with our partners and other Federal agencies, CDC collects data and conducts research on youth use of tobacco products. For example, CDC and FDA jointly administer the NYTS, an annual survey to monitor national trends in the use of tobacco products among U.S. students in grades 6 through 12. This survey has been essential in identifying the extent and scope of the current youth e-cigarette epidemic in this country. CDC also complements its routine surveillance efforts with novel, rapid response monitoring that captures emerging trends concerning e-cigarettes, including through the use of sales data to monitor sub-annual changes in the United States e-cigarette marketplace. In addition, the Tobacco Laboratory in CDC's Environmental Health Laboratory provides critical laboratory science, including measuring harmful and addictive constituents in e-cigarette solutions and aerosol, and measuring chemicals in the blood and urine of people who use e-cigarettes or are exposed to secondhand aerosol.

CDC has been at the forefront of this issue for many years. In 2013, CDC published a report highlighting a doubling in youth e-cigarettes use during 2011–2012, which initiated our efforts to warn the public, and others, about the health risks of e-cigarette use among U.S. youth. Since then, CDC has continued those efforts. For example, in 2016, CDC collaborated with the Surgeon General to release a Surgeon General's report entitled "*E-Cigarette Use Among Youth and Young Adults*." This was the first comprehensive Federal report on e-cigarettes among young people. Since then, CDC has continued to promote the findings of the report to educate parents, influencers of youth, and youth themselves. In response to compelling data about the sales and increased market share of JUUL, reports of widespread teen use of this and similar products, and mounting public concerns, CDC launched a partner initiative to expand the reach of CDC public health warnings. CDC developed plain-language infographics and social media posts for public health organizations and consumer audiences about e-cigarettes and has conducted back-to-school social media campaigns. CDC was the primary Federal agency that assisted the Office of the Surgeon General in writing and launching a December 2018 e-cigarette advisory to bring awareness to relevant audiences (teachers, parents, clinicians) about e-cigarette use by young people. CDC also developed promotional materials to support the release of the advisory.

CDC provides funding and technical support to all 50 states, the District of Columbia, 8 U.S. territories, 12 tribal support organizations, and 8 national networks representing priority populations, which are essential for coordinating the public health response to prevent tobacco initiation among youth and young adults, promote quitting among youth and adults, eliminate secondhand exposure to smoke and e-cigarette emissions, and identify and eliminate tobacco-related disparities. With funding from CDC, state and territorial health departments have taken a number of approaches to reduce youth access and exposure to e-cigarettes, including preparing nicotine health advisories and tobacco-free school toolkits, conducting surveillance of tobacco product use among youth, and creating and disseminating evidence-based educational materials to the public through social media and other mechanisms. CDC has ongoing work to prevent and reduce tobacco use, including e-cigarettes.

CDC's Efforts to Understand the Harms Associated with Marijuana Use

The exposure to vaping products containing THC in most patients in this outbreak underscores the need to better understand the health effects of increasing marijuana use in the United States and the changing marketplace as states continue to pursue legalization of marijuana for medical and nonmedical purposes. According to the 2018 National Survey on Drug Use and Health, more than 43 million (16 percent) Americans age 12 years or older reported using marijuana in the past year. Marijuana use among youth and young adults is particularly concerning given the potential risks to the developing brain. In 2018, one in eight youth, aged 12 to 17 years, and one in three aged 18 to 25 years reported marijuana use. Prolonged heavy marijuana use has been associated with a broad range of health effects, and

health effects have also been documented in young people, in particular those that initiated marijuana use at an early age.

CDC data indicate that many youth who use e-cigarettes also report using marijuana in vaping devices. For example, data from the 2016 National Youth Tobacco Survey found that one-third of U.S. youth who have ever used an e-cigarette or other vaping product reported using marijuana in an e-cigarette or other vaping product, including approximately one-quarter of middle school users.

CDC conducts limited surveillance, monitoring, technical assistance, and public education related to marijuana. For example, a small number of questions regarding marijuana use are included in the Youth Risk Behavior Survey (YRBS) and are being asked in a limited number of states through the Behavioral Risk Factor Surveillance System (BRFSS) and the Pregnancy Risk Assessment Monitoring System (PRAMS). In addition, CDC is providing informal technical assistance to state, local, tribal, and territorial officials when requested, with a focus on preventing harms, particularly in vulnerable populations such as youth, young adults, and pregnant women. CDC's marijuana webpage (*www.cdc.gov/marijuana/*) provides information on health effects, data and statistics, and offers resources and tools for the public. Finally, CDC collaborates with other Federal agencies on scientific workgroups to address emerging issues and work toward consensus on indicators and measures to monitor marijuana use and health effects.

CDC Interim Outbreak Recommendations for Providers, States and the Public

CDC continues to refine recommendations based on data and scientific findings emerging from this complex outbreak. To date, no single compound or ingredient has emerged as the cause of EVALI, and there may be more than one cause. Because most EVALI patients report using THC-containing products before the onset of symptoms, CDC recommends that persons should not use e-cigarette, or vaping, products that contain THC. Persons should not buy any type of e-cigarettes or other vaping products, particularly those containing THC, off the street and should not modify or add any substances to e-cigarettes or other vaping products that are not intended by the manufacturer, including products purchased through retail establishments. In addition, because the specific compound or ingredient causing lung injury is not yet known, and while the investigation continues, persons should consider refraining from use of all e-cigarettes or other vaping products. Regardless of this investigation, e-cigarettes or other vaping products should never be used by youths, young adults, or women who are pregnant. Adults who are using e-cigarettes or other vaping products to quit smoking should not return to smoking; they should weigh all risks and benefits, and consider using FDA-approved medications. Updated information and recommendations related to this investigation are available at *www.cdc.gov/lunginjury*.

Conclusion

CDC's foundation of public health work, including direct relations to state and local governments, is essential to our Nation's ability to respond to expected, unexpected, and unimaginable threats. CDC prioritizes sharing critical information with clinical providers, public health departments, laboratories, and the public to help prevent additional EVALI cases and to rapidly identify and treat affected individuals. We remain fully committed to investigating and analyzing data as quickly as possible and using cutting-edge science to inform evidence-based recommendations to protect the public from this health risk. CDC is working around the clock, together with state and local health officials and FDA colleagues, to identify the cause or causes of this outbreak and will continue to keep Congress, and the American public, up to date on our progress in this rapidly evolving investigation.

The CHAIRMAN. Thank you, Dr. Schuchat. We will now begin a five-minute rounds of questions. My first question is what advice should I give Tennesseans? Dr. Schuchat, you repeated that CDC recommends don't buy any e-cigarette or vaping products off the street, don't modify—that would be the type of oil that you mentioned for example—don't modify the product. But the only way to assure, CDC says, that you are not at risk while the investigation continues is to consider refraining from use of all e-cigarettes or

vaping. So is CDC's advice that one should not use e-cigarettes right now during the investigation?

Dr. SCHUCHAT. We are a data-driven organization and so our strongest recommendation right now is to avoid using e-cigarette or vaping products that contain THC, and to avoid getting such products from informal sources like friends or dealers or online. But because about 10 percent of the cases of this very severe lung injury do not have a history of vaping THC, we continue to suggest that people consider refraining from use of all e-cigarettes or vaping products.

The CHAIRMAN. Mr. Zeller, your—FDA's own website is similar in the respect that it says FDA warns the public to stop using THC, the derivative of marijuana that makes you high, and any vaping products off the street and oils like the acetate, but you don't go on to say that you should consider refraining from using any e-cigarettes during this period of time. And in fact, the FDA allows the sale of these e-cigarettes because you delayed for several years the requirement that a manufacturer apply for standards. So which advice should Tennesseans follow the CDC's or the FDA's?

Mr. ZELLER. I believe our website is consistent with the CDC website and that it contains that second point about, during the pendency of this investigation, if you are concerned about any safety issues that you should consider refraining from using any e-cigarette or vaping product.

The CHAIRMAN. Yes, but you said in your testimony that it was not legal to sell e-cigarettes but in fact, it is only legal to sell e-cigarettes in a convenience store, for example, because the FDA hasn't stopped it.

Mr. ZELLER. That is correct. That is a separate issue. These products remain on the market through a continuing exercise of what is known as enforcement discretion by the Agency. That is separate and apart from the public health advice to people concerned about what is going on with pulmonary illness and on that issue, I believe that our website is completely consistent with CDC's as is our messaging.

The CHAIRMAN. Well, but it is—you are not saying to a convenience store that their selling e-cigarettes is illegal right now, right?

Mr. ZELLER. These products remain on the market through enforcement discretion. What is completely illegal is the sale of these products to anybody under the age of 18. And what I tried to say in my remarks is that we have been aggressively enforcing the youth access restrictions for e-cigarettes from the day that we gained regulatory authority over these products.

The CHAIRMAN. Well, obviously, we are not making much progress with youth use. You list a number things you are doing and 1 in 4 of American high schoolers according to your statistics are using e-cigarettes. How much of the more than $5 billion that you have collected from tobacco companies over the last 10 years have you used to discourage young people from using e-cigarettes?

Mr. ZELLER. The investment that we made in public education is a dollar figure that we can separate out for e-cigarettes. And from late 2017 through the end of next year we will wind up investing about $150 million in a massive multimedia public education campaign to get the word out to kids. Kids know that cigarettes are

dangerous. We have made great progress in reducing kids use of conventional combustible cigarettes.

What we have learned from our research is that most young people walk around thinking that e-cigarettes are harmless, that it is just a water vapor. There are surveys that show that kids don't even know that nicotine is present in the aerosol. We are working very hard to get the message out through paid advertising on TVs——

The CHAIRMAN. One other, if I may so I could stay within my time. When do you expect the rules, the two rules that you have proposed, to be final?

Mr. ZELLER. We are going very hard to finalize them. The second of those rules, the rule for the pre-market tobacco application process, that is a proposed rule where the common period is still open through the end of the month but I can assure the Committee that completing these two final rules are the highest priorities of the Agency and the Department.

The CHAIRMAN. Senator Murray.

Senator MURRAY. Thank you, Mr. Chairman. Mr. Zeller, I was actually shocked that in a hearing that is focused in part on youthful vaping epidemic, your testimony, both written and oral here, made no mention of the administration's September 11th announcement that it intended to clear the market of all unauthorized non-tobacco flavored vaping products. It was made with a lot of fanfare and many of us have been publicly urging you to finalize it. Why is that not included in your testimony?

Mr. ZELLER. The only thing I can say, Senator Murray, is that we are committed to doing everything that we can to prevent kids from using any tobacco product including e-cigarettes, and that we are continuing to develop a policy approach that aligns with that concern.

Senator MURRAY. I appreciate that but the September 11th announcement was one we all listened to, we were attentive to, we have been pushing you on it, and yet here we are talking about the very topic and you didn't mention it in your remarks. I don't understand why.

Mr. ZELLER. I think that any questions that the Committee has about the announcement that the White House made and anything related to what remains a deliberative process on policy is best referred to the White House itself.

Senator MURRAY. This is a White House decision?

Mr. ZELLER. I would refer the Committee to the White House if there are any questions about this ongoing deliberative process.

Senator MURRAY. Okay. Are you committed to finalizing the flavor compliance policy that the administration announced, yes or no?

Mr. ZELLER. We are absolutely committed to coming up with a policy that aligns with this epidemic use of e-cigarettes by kids and that addresses this fundamental problem.

Senator MURRAY. What is your timeline, when?

Mr. ZELLER. I can't give you a specific timeline, Senator, other than to say that the deliberative process continues.

Senator MURRAY. You being told not to do this?

Mr. ZELLER. You are asking about the deliberative process and I really would refer you and the Committee to the White House to ask specific questions about where we are.

Senator MURRAY. Okay. Dr. Schuchat, in September shortly after the administration's announcement, Representative Presley asked you, "to be effective, do you agree that the flavor ban needs to include mint and menthol?" Your answer was yes, and since then two things have happened. First, it has been reported this administration is dramatically weakening the policies, working on including by carving out those menthol products and covering only some retailers or walking away from the policy altogether.

Second, DHARMA published CDC data demonstrating the increasing popularity of menthol and mint flavored e-cigarettes among youths while JAMA published data examining differences between mint and menthol attracting young people. So I want to ask you Representative Presley's question again. To fully protect kids, does this administration's ban of unauthorized flavors need to include mint and menthol products and cover everywhere that kids currently buy these products?

Dr. SCHUCHAT. We know that flavors are particularly attractive to youth. The CDC, FDA National Youth Tobacco Survey didn't differentiate menthol or mint. We don't even know if kids can differentiate menthol or mint. But the question that was asked was about menthol or mint and that was a very popular choice. The use of that flavoring increased after Juul took away the candy flavors. So the use of—we believe that kids are likely to use whatever flavor is left.

Senator MURRAY. Yes. So does CDC's data actually suggest if a young person's preferred flavor e-cigarette is no longer available—for example, this administration bans fruit flavor but leaves menthol products on the market, kids will just simply switch to another flavor?

Dr. SCHUCHAT. Based on what we saw in 2018 to 2019, that is what we would expect.

Senator MURRAY. Okay. Mr. Zeller, I know that FDA and CDC are working hard to identify the causes of the outbreak of the vaping related illnesses and contain this crisis. I want to underscore how important that work is for families everywhere. I am also very focused on how we could have prevented this outbreak in the first place because unfortunately the administration gave e-cigarette companies a free pass for four years to market many of these products with no FDA review. I want to ask could the national outbreak that has sickened thousands have been avoided or minimized if FDA had required pre-market authorization of e-cigarettes last year as the Agency originally envisioned?

Mr. ZELLER. I can understand why you are asking that question. I think it is a very difficult question to answer even in hindsight. Recall that the overwhelming majority of the cases of illness and death involved the use of THC. We are not saying that it is only THC related but it certainly seems to be overwhelmingly THC related.

Senator MURRAY. I understand that. But do you think that the market for these vaping devices that are also now being used for

marijuana would have existed in the way it has done today had it not been for FDA's delay?

Mr. ZELLER. I think that even under the original compliance policy that we had in the final deeming rule from 2016, these products would have remained on the market well into 2019 and that was under the original compliance policy. Again, I can't go back in a time machine and say how things would have been changed. We are a regulatory Agency that follows the regulatory science.

As I said in my written and oral remarks, the decision that we made in 2017 to extend the deadlines was made at a time when kids use of e-cigarettes was in decline. We immediately revisited that policy a year later when we saw the spike, as the Chairman has pointed out in the chart, to revisit what those deadlines should be.

Senator MURRAY. I can't help but think that the review of those products by FDA would have provided consumers with some pretty critical clarity. So it is—we are where we are, but it is really disconcerting.

The CHAIRMAN. Thank you, Senator Murray. As I mentioned earlier, we have votes at 11 a.m., but we will continue the hearing through the votes so that Senators can have time to ask their questions. We have very good attendance today. So I would like to encourage Senators to stay within the five minutes for questions and answers.

Senator Enzi.

Senator ENZI. Thank you and thank you for holding this hearing. We are talking about vaping as the new crisis. I am still concerned about cigarettes. In 2009 when we passed the bill, I was really concerned to get three amendments. And one was increased fines. I don't know how that is working because—the second requirement that I got in there was one that we would get a report three years after we passed it and every two years after that to see if we are making progress or not.

We got a report once in 2013. So it makes it hard to know how we are doing on that and wouldn't give me much confidence in what we are doing with vaping. Can you commit, Mr. Zeller, to issuing a new report as soon as possible and meeting your statutory obligation to report to Congress every two years going forward?

Mr. ZELLER. Absolutely, Senator. We are working hard on updating and submitting the most recent report. And I can assure you on the enforcement authorities that you got into the underlying statute which gave the Agency an authority that it previously had never had, which is for the ultimate retailer that continues to break the law and sell to kids, thanks to the Family Smoking Prevention and Tobacco Control Act, we now have the ability for a retailer that has a certain number of violations in a specified period of time to go before an administrative law judge to seek something called a note tobacco sells order. And unfortunately, we have had to do this over 150 times to prevent retailers from selling any tobacco products of any kind for a specified period of time.

Senator ENZI. Thank you. I won't take all the time to find that when that report could come out but I will be submitting that in writing. Another thing that I got in there was one where there had

to be color graphic warning labels and the courts of course struck that down. They said that it was taken to court and the court said that it was an unabashed attempt to evoke emotion and perhaps embarrassment and browbeat consumers into quitting rather than purely factual, accurate, or uncontroversial information. Yes, the purpose of it was to get people to quit smoking and I think the reason it went to court is because it was working. So I congratulate you on an attempt to do color graphic warning labels.

I think these warnings would be a good way to get people to stop smoking or vaping or never start. Can you explain the reasoning behind the choice to focus on highlighting the less known consequences of smoking like diabetes and bladder cancer rather than enhance awareness and remind smokers of the association between smoking and lung cancer, heart disease, or chronic obstructive pulmonary disease?

Mr. ZELLER. Thank you for the question, Senator Enzi. And yes, the focus of the new cigarette health warning proposed rule that we issued several months ago is focused on some of the lesser known but still very serious health consequences of smoking. We took that approach in the aftermath of the court case that ruled against the original final cigarette health warning rule, as you described in your statement, taking into account legal, constitutional, primarily First Amendment considerations as we researched and then drafted a new proposed rule that we intend to finalize by March of next year under a separate court order deadline.

The focus is helping the public, adults and kids, understand that there are some lesser-known health consequences with cigarette smoking and that was a deliberate, strategic move on our part with an eye toward when this rule goes final, in the event that there is litigation, that this will give us the best chance of surviving that court challenge.

These are all serious health conditions and they turn out to be lesser well-known than things like heart disease and lung cancer. And our research shows that the public is largely unaware that those can be linked to cigarette smoking.

Senator ENZI. Thank you. I also am interested, of course, the testing is still ongoing but there is information on THC that is present in the majority of the samples the FDA has tested. Does the FDA have jurisdiction over THC products? And if so, what is the authority?

Mr. ZELLER. I think on a case-by-case basis when it comes down to the fact, if we were to take an action because of the presence of THC, it would be because the investigation has continued because we are going after the supply chain here. How did these products get onto the market in the first place? We are not looking at possession. We are not looking at personal use of these products. We have investigators on the ground to try to get at how did they get into the chain of distribution and commerce in the first place. If we can identify the responsible party—because with THC we are talking about an illicit compound.

It is not like someone is going to step forward and say yes, I did it. If we can find the responsible party, if we can do the product analysis that shows that the THC is present with or without these oils that seem to be making it worse, then in theory we could use

authorities that we have under the Food, Drug and Cosmetic Act. We are also working in consultation with the Justice Department and the Drug Enforcement Administration because THC is a controlled substance and there could be DEA authorities, but I don't want to speak for DEA. But we could act depending upon the facts under Food and Drug authorities.

Senator ENZI. Thank you. I apologize for running over.

The CHAIRMAN. Thank you, Senator Enzi.

Senator Baldwin.

[No response.]

The CHAIRMAN. Senator Hassan.

Senator HASSAN. Well, thank you, Mr. Chairman and Ranking Member Murray for having this hearing and thank you to both of our witnesses and please pass on our thanks to the men and women you work with for their dedication to service. As other Senators have mentioned, recent national youth tobacco survey data shows an alarming rise in e-cigarette use among middle and high school students. And according to the CDC Youth Risk Behavior Survey, my State of New Hampshire has the highest percentage of high school students in the Nation reporting daily e-cigarette use. Millions of children are nicotine dependent because of e-cigarettes and the American Academy of Pediatrics estimates that only 4 percent of those kids are going to successfully quit. That is a stunning statistic.

The devastating impact companies like Juul have had on children must be at the forefront of FDA's review of their pre-market tobacco product applications in May. So Director Zeller, I have four questions for you I am hoping to get to in our four minutes. When the flavor ban was announced in September, Juul publicly stated that it would not lobby officials or attempt to influence the policy as it was developed. However, Juul executives recently told my staff that they have had, "a number of conversations with FDA since the September announcement." Were you aware of or part of any of these conversations? And if so, what was discussed?

Mr. ZELLER. I am unaware of any policy related discussions between Juul and FDA.

Senator HASSAN. Any policy related. Have there been discussions between Juul and FDA that you are aware of?

Mr. ZELLER. We have been given a heads-up on personnel changes and things unrelated to policy.

Senator HASSAN. But in terms of policy, you are saying you are unaware?

Mr. ZELLER. I am unaware of any conversation.

Senator HASSAN. Okay. Given the importance of this issue. It is really concerning that you may not be aware of the full scope of conversations that Juul officials say have occurred with your staff. So I will follow-up in writing to request that you provide more information about what has been discussed in these meetings and with whom. Second question.

A recent study in the Journal of the American Medical Association found that mint is the most popular e-cigarettes flavor among high school students. Earlier this month, former FDA Commissioner Scott Gottlieb predicted that if menthol is exempted from the flavor ban, Juul will simply rename their current mint flavor,

which does contain some menthol, and sell it as menthol. So Director Zeller, how will FDA ensure that companies like Juul cannot game the flavor ban by, for example, reclassifying their mint flavor as a menthol product?

Mr. ZELLER. Senator, it is really difficult for me to get into a policy discussion when we remain in the deliberative process in creating the policy. So let me try this to speak hypothetically about product name change.

Senator HASSAN. Yes.

Mr. ZELLER. It turns out that under some litigation that went against the Agency, it may be possible for companies to change the names of products. In a world where we—again, hypothetically, in a world where we had a policy in place that tried to get at I think what is embedded in your question or any company to try to simply change the name of a product to be able to keep a product on the market that would otherwise have to be removed from the market, I will just say hypothetically in that situation FDA would be very concerned and would look at whatever authorities that we had to take action. But that is only a hypothetical——

Senator HASSAN. I understand it is a hypothetical. I understand the deliberative process argument but let me be clear what you are hearing from everybody up here is that we have children who are getting hooked on these products. There has been a lot of delay. We are looking for a strategy and we are looking for you guys to move through your deliberations.

You have had plenty of time already and kids and people, Americans all over this country, are being hurt and they are going to be—they are addicted. And when the American Academy of Pediatrics tells me that only 4 percent of the kids who are now addicted to nicotine are going to be able to quit, your deliberative process needs to be as fast and strategic as it can be. The White House announced a policy back in September, but now we are being told they are still deliberating.

We need you guys to focus on this. I have 25 seconds left but let me tell you what I want to get at in my last two questions, which is about the data that you all are collecting. Juul told my office that they regularly submit data on Juul purchasers to FDA. Of course, submitting purchaser data rather than user data means Juul does not submit data on youth e-cigarette use.

Will FDA require Juul to submit their user data, inclusive of youth users, rather than just purchase or data as part of their premarket tobacco product application? And this also would be useful to get at the issue of diversion. Who is purchasing but then who is using?

Mr. ZELLER. A couple comments, Senator. First——

The CHAIRMAN. Mr. Zeller, I am going to ask you to be succinct in your answer or give a written answer.

Senator HASSAN. Thank you.

Mr. ZELLER. Two points and then I will elaborate in writing. We have an active ongoing investigation of Juul. All aspects of advertising, marketing, and promotion of their products. So that is an ongoing investigation. Your question about the application process is a separate question and it is clear under the law that Congress wrote that as we review any application for any product, the im-

pact on initiation, the impact on the likelihood that any non-user starting with kids would use the product, is a core component of how we would review any application for any new tobacco product.

Senator HASSAN. Thank you, and thank you, Mr. Chairman, for your indulgence.

The CHAIRMAN. Thank you, Senator Hassan.

Senator Burr.

Senator BURR. Mr. Chairman, I start with the unanimous consent request to enter into the record the GMO study that Senator Hassan just referenced to. And I will note for my colleagues, this is the first time menthol has been broken out. They use Juul data to do it. It is referred to as monitoring the future of which menthol data in eighth graders was 1.7 percent, 10th graders 2.4, 12th graders 3.8.

The CHAIRMAN. So ordered.

[The following information can be found on page 52.]

Senator BURR. It is important to distinguish between menthol because the mint number is huge, the menthol number is not huge. There is not a mint product in combustibles and Mr. Zeller I think you will agree that when we did CTP, it was with the intent to bring less harmful products so that adults could choose to switch from combustibles to innovative products of which e-cigarettes were one of them.

To maintain that there is the ability to go from a menthol combustible to a menthol non-combustible is an important health advantage to the American people to have reduced harm products. Now, Ms. Schuchat, I asked HHS for information related to the CDC's Youth. Tobacco Survey. September 13th, I asked for it to be a response by September 27th. I have not received it. Your staffs got that information. Will you promise me today I will have this next week?

Dr. SCHUCHAT. We have published that data. So that was in the—you just mentioned the monitoring the future data. The other report in JAMA of the same issue was the National Youth Tobacco——

Senator BURR. I have got that JAMA report but specifically there is some information I have asked of HHS on the youth access.

Dr. SCHUCHAT. Yes, we will go back and get you that but just to expand on your comment, the question on the monitoring the future was, what is the usual—which Juul flavor do you use most often? So individuals could just give one choice, not multiple.

Senator BURR. That is correct. April 10th, 2018 CDC made an initial announcement of an E. coli outbreak with an unknown source. Eight days later, the Agency determined the outbreak was linked to a specific product from a specific region, romaine lettuce, Yuma, Arizona. The CDC determined this link in part on interviews with those who had fallen ill and found that of 28 people 93 percent had eaten romaine lettuce in the last week. CDC acted swiftly and decisively in that.

Now, we are at a point where 80 percent of patients use THC products and CDC just recently announced a form of vitamin E calling it a chemical of concern. That is based on CDC's determination based on 29 samples of similar number to the romaine lettuce

investigation. What additional information does CDC need to make a determinative cause?

Dr. SCHUCHAT. We are extremely concerned about vitamin E acetate in the THC containing products but what we cannot say right now is whether there are other substances. There are about 10 percent of the patients with this very severe lung injury who did not use the THC.

Senator BURR. You came to a single conclusion on Ebola—I mean an E. Coli. In a number of days, specifically with the same population, and I would only suggest to you that it is time to take the information you have got. And at least put out the warning a little more specific than maybe what you have. I have only got a minute left. I need to go to Mr. Zeller. Has the FDA inspected vape shops? And when I ask that question, I separate vape shops from traditional retail outlets.

Mr. ZELLER. Yes, we do.

Senator BURR. How many have you inspected?

Mr. ZELLER. I will give you the exact number in writing. I don't know the exact number at the top of my head, but we——

Senator BURR. Does FDA have authority to investigate them?

Mr. ZELLER. Yes, we do.

Senator BURR. Okay. And when FDA deemed vapor products as tobacco products the Agency started to inspect vape shops. As FDA began to sound the alarm bell on children's use of these products, from 2017 2018 did CTP invest more money in inspection of retail facilities?

Mr. ZELLER. I will get you the annual numbers in writing. What we did——

Senator BURR. Let me tell you the number. You actually decreased inspections from $48.4 million in 2017 to $44.3 million in 2018. Did CTP conduct more inspections of retail facilities to determine whether they are selling products to youth?

Mr. ZELLER. My recollection is that the relative number of inspections stayed the same. What we had was a little bit of efficiency. These are contracts that we have at the state and local level and there were some efficiencies——

Senator BURR. These are your responses to me. You had 22,000 fewer inspections in 2018 than you did in 2017.

Mr. ZELLER. Senator, the point that I am trying to make is, when we got regulatory authority over e-cigarettes in the summer of 2016 for the first time, what we did with that existing contract mechanism was reprioritized where the inspectors would go to see if retailers would or would not sell the newly regulated products starting with these e-cigarettes to kids.

Senator BURR. This one is an easy one. Did you increase or decrease the education campaign investment from 2017 to 2018?

Mr. ZELLER. From 2017 to 2018, our investment in the public education campaign has gone up considerably. From 2017 through the end of 2019, we will be investing roughly $65 million in that campaign and $85 million next year.

Senator BURR. Let me tell you how you responded to me in a written response. You decreased your public education campaign investment by $72 million from 2017 to 2018. You can find that in

question 14 of CTP's oversight letter that I received a response to on January 11th, 2019.

Mr. ZELLER. Senator, what I was referring to was the investment in the public education efforts for e-cigarettes, which has increased.

Senator BURR. Okay. To my colleagues, it is important for us to be dealing with the same facts on these issues. I remind our colleagues, until Congress decides that tobacco is an illegal product, one of the responsibilities we have as Members of Congress is to protect the adults choice to use these products. That decision has not been made that it is an illegal product and we have done everything we can to try to bring reduced harm product to the marketplace. I think that is a good public health issue.

Somebody will probably ask today, why don't more companies do pre-market tobacco applications? And the fact is that statutorily it requires CTP to review those in 180 days. Currently, there are three applications that may have been resolved but they are at 625 days. Six applications are at 589 days. Four applications at 191 days. So when you ask why aren't companies willing to go out and do it? It is the lack of clarity of the pathway and it is the performance with a statutory requirement of 180 days that it is a black hole that you fall into.

The CHAIRMAN. Senator Burr, we will have a second round of questions if you——

Senator BURR. I thank the Chairman and I thank the Members for their indulgences. I yield the balance of my time.

The CHAIRMAN. Okay. Thank you, Senator Burr.

Senator Baldwin.

Senator BALDWIN. Thank you. Children's Hospital of Wisconsin was the first in the country to publicly identify what was at the time a mystery illness connected to vaping found in 8 teenagers who were hospitalized with seriously damaged lungs. In response, I requested that the CDC establish an Emergency Operation Center to investigate the cause of the outbreak and support states in their response. And I urged this Committee to hold a hearing on this matter. So I am pleased that we are here to discuss both the outbreak of this illness as well as the increasing number of children using e-cigarettes. It is very clear that our work is far from over.

Now that the CDC has detected one potential chemical of concern, the Committee I think should also hear from individuals who are on the front lines who can speak to the challenges of identifying, containing, and preventing outbreaks. And I expect we will learn more today that will indicate further action. At Children's Hospital of Wisconsin, many of the children with these injuries were hospitalized in intensive care units and they required supplemental oxygen or mechanical ventilation to breathe.

Dr. Schuchat, can you tell us what is currently known about the long-term impact of these injuries, and especially what we might anticipate in terms of the impact on young people. And what resources does the Center for Disease Control and Prevention need to conduct further research on the longer-term impacts of this illness?

Dr. SCHUCHAT. Yes, thank you. And first just to say, we really applaud the clinicians in Wisconsin who sounded the alarm and got

us going on the response. This is a very difficult injury that young people are suffering. You may have seen reports of the first reported lung transplant in a 17 year old in Michigan.

Mr. ZELLER. Double transplant.

Dr. SCHUCHAT. Double transplant. Thank you. So we know that some individuals will have very long term damage and not even be able to breathe without new lungs but we don't have the full story on the spectrum of illness or injury or how people will do. We have been working with the pulmonary specialty community to get guidelines out for follow-up so that everyone who is discharged from the hospital gets a regular follow-up including lung pulmonary function tests.

Importantly, we are urging people to make sure that they focus on cessation and counseling while people are still in the hospital. There are tragically a few reports of readmission for worsening after discharge. In terms of the resources needed, this is a newly recognized syndrome in terms of this outbreak and so the full scope of research questions exist, not just the long-term outcome. The best way to treat it, the best way to track it.

Right now we are using syndromic surveillance to try to find more automated ways to detect trends. We are worried about the impact that influenza may have on people who have suffered from this injury. Whether they are going to be new treatments needed or new challenges with diagnostics. So I think CDC, FDA, and NIH together joined in a meeting that tried to lay out a research agenda for the issue.

Senator BALDWIN. Okay. Mr. Zeller, I believe that the marketing practices of these vaping product makers have played a role in the popularity of these products, especially among youth. And a study of Juul's advertising efforts from Stanford University School of Medicine found that Juul's advertising imagery in its first six months on the market was patently youth-oriented, to quote from the article.

That advertising was widely distributed on social media channels frequented by youth and was amplified by hashtag extensions and catalyzed by compensated influencers and affiliates. For too long FDA has failed to take action to crack down on the marketing aspect of this and advertising targeted at our Nation's young people. So can you explain why the FDA did not issue specific marketing guidance to e-cigarette manufacturers when these products first started coming to the market?

Mr. ZELLER. When e-cigarettes were first on the market, we didn't have regulatory authority over them. Since we got that regulatory authority which began in the summer of 2016, we have used all of our enforcement tools. We have issued warning letters for e-liquids that resemble kid friendly foods, like juice boxes, cereal, and candy. We have issued warning letters for paid social influencers where the connection to the company wasn't revealed and those statements lacked required warnings. We have issued a warning letter to Juul for unauthorized modified risk tobacco product claims. So we have tried to use all of the available tools that we had once we had the regulatory authority over these products.

Senator BALDWIN. Well, the warning letters are not the same as sort of a wider marketing guidance. I appreciate hearing you repeat

what you had in your testimony, but the FDA has delayed taking real action. In September, it was announced that the administration or by the administration that you would be clearing the market of unauthorized non-tobacco flavored e-cigarette products and it has been two months. So where is the policy?

Mr. ZELLER. I think——

The CHAIRMAN. Mr. Zeller, I would like to ask you to make that succinct in writing.

Mr. ZELLER. I think any questions about the current state of policy really needs to be directed to the White House. We are in a deliberative process. The White House made an announcement in September and we are working to advance a policy consistent with taking steps to do everything that we can to protect kids from these products.

The CHAIRMAN. Thank you, Senator Baldwin.

Senator Paul.

Senator PAUL. They say politics is the art of looking for trouble, finding it everywhere, diagnosing it incorrectly, and applying the wrong remedies. I am afraid we could get into the same problem here in this discussion. The problem seems to be, and I have a great deal of sympathy, I have kids and I have warned them about, the vaping of illegal products, but it seems to be primarily deaths and horrific medical problems from vaping illegal products.

What we are going to do in response to that is make more vaping illegal. It seems kind of counterintuitive. It seems like if you make more things illegal, maybe you get more people vaping illegal products and you have more problems. I think to have a complete picture here we ought to look at things in totality and it would have been nice to hear from somebody testifying about lives saved from vaping. You know, 480,000 people die from smoking each year, 2,000 people are dying from vaping illegal products, and I don't want to discount that, we should do something about it, but I am not so sure making flavors illegal is actually going to make the problem better.

It might make the problem worse. So we have to think about what we are doing here. And we really ought to ask the question and seriously look at, are lives being saved from vaping? I think there are estimates that hundreds of thousands of lives have been saved over the past 12 years from vaping instead of smoking. Now, you say well kids, is not a good idea to have kids vaping, for one reason or another. Yes, that is probably true, but it is already illegal for kids to vape. If you want to get more kids not to vape, well we may increase the penalty on people selling to kids. But to get rid of them, most adults are using the flavors as well.

If you say well you are more likely to use the vaping flavors to get off of smoking, maybe you are more likely to stick with smoking if you ban flavors. So I just think—it is like so many things, we get off strung out on these things and we want to react, react, react really quickly, but nobody is really asking one important question, how many lives are being saved? The lives from smoking deaths dwarf any of the problem. It is a terrible problem we are having. I am not discounting it but it is a problem from illegal THC.

We are going to make more things here legal. So we drive the flavors to the underground market. Maybe then people are going

to cut the flavors with vitamin E as well. So I really just think like so many things we get going on this and we are probably going to end up doing the wrong thing. But if you want less kids to smoke, I would just increase the penalties on people selling the kids and you might have less kids smoking.

But banning the flavors, you are going to affect the adult market also, and as a secondary consequence, you may also affect the amount of people that are able to convert from smoking to vaping and saving lives. I don't have a direct question but thank you.

The CHAIRMAN. Thank you, Senator Paul.

Senator, Kaine.

Senator KAINE. Thank you, Mr. Chairman. And before I get to the questions, I was going to ask Mr. Zeller, I was not happy with your answer to Senator Murray's question about the pendency of the regulations after the September 11th announcement. The title of this hearing that we all know, Examining the Response to Lung Illnesses and Rising Youth Electronic E-Cigarette Use. You are the Director of the Center for Tobacco Products at the U.S. Food and Drug Administration.

When you were asked by Senator Murray about the announcement that the administration made in September, you referred us to the White House. The White House won't send witnesses here. The White House is instructing witnesses to ignore subpoenas from Congress about testifying. You knew what the title was and you have the job. And I think we are entitled to an answer from you. I am not going to ask you about the deliberative process or details, but I want to just read this to you.

This was the announcement that was made by the White House, September 11th, titled, Trump administration Combating Epidemic of Youth E-Cigarette Use With Plan to Clean Market of Unauthorized Non-tobacco Flavored E-Cigarette Products. First paragraph, today the Trump administration announced that as part of its ongoing work to tackle the epidemic of youth e-cigarette use, the FDA intends—the FDA, your Agency—to finalize a compliance policy in the coming weeks that would prioritize the Agency's enforcement of the pre-market authorization requirements for non-tobacco flavored e-cigarettes, including mint and menthol, clearing the market of unauthorized non-tobacco flavored e-cigarette products.

A quote from Secretary Azar in this release, "the Trump administration is making it clear that we intend to clear the market of flavored e-cigarettes to reverse the deeply concerning epidemic of youth e-cigarette use that is impacting children, families, schools, and communities. We will not stand idly by as these products become an on-ramp to combustible cigarettes or nicotine addiction for a generation of youth."

Is that still the Trump administration's intent to clear the market of flavored e-cigarettes to reverse the deeply concerning epidemic of youth e-cigarette use?

Mr. ZELLER. I understand your question, Senator Kaine, and the frustration about my inability to share more detailed information on——

Senator KAINE. I am not asking about the details. I am not asking about the plan. I am not asking about the timing. The administration announced that your Agency, and you are the chief official

over tobacco at this Agency, that it was the intent of the administration to issue regulations clearing the market of unauthorized flavored e-cigarettes. Is that still the intent of the administration?

Mr. ZELLER. All I can say Senator is that we are continuing to advance the policy to address——

Senator KAINE. Let me ask you this. Do you know the answer to my question?

Mr. ZELLER. There is no final answer as of now.

Senator KAINE. There is one of two options, you either don't know what the Trump administration intends, you don't know whether they will honor what they said we will do, or you know what the intent is and you are not telling me. Which is it? Do you not know or do you know and you are not telling me?

Mr. ZELLER. There is no final answer on the policy question. It is why we continue to have these discussions internally.

Senator KAINE. That again, there may not be a final answer but the Trump administration announced its intent it was going to clear the market of these flavors. Do you have any reason to believe that the intent is now different?

Mr. ZELLER. Well, all I can refer you to Senator is as we continue to work on the policy to address the problem with kids' use of e-cigarettes——

Senator KAINE. I am not asking about the total. I am asking about an announcement that was made about your Agency's actions and whether the intent that the administration announced is intent of the administration.

Mr. ZELLER. The goal remains——

Senator KAINE. I do not like being playing games with. I do not like saying get somebody from the White House to answer the question when the White House will not send two witnesses to hearings like this. You are the person responsible. You should know the answer to this question because you knew what the title of the hearing was and you have the job. Let me move on now to another topic. I have a lot of folks who have spoken to me about this issue. I have got a student from Arlington, Nathan Robinson, who is here with one of his mentors.

I have been told by kids in Virginia that they researched to see whether their e-cigarettes are harmful and as soon as they Google to get health information, then they are flooded with ads from companies trying to sell them e-cigarettes. I have school administrators who tell me we don't have a lot of experience in helping 14 year olds break addictions.

The 17 year old that you mentioned, Dr. Schuchat, had a double lung transplant, the first that has been done for a vaping illness. The average life expectancy after a double lung transplant is seven years. That is the average life expectancy. We should get an answer to this question about whether the administration is going to honor the policy that they announced or not.

Let me ask you this as I conclude. There is a proposal on the floor of the Senate that this Committee voted out as part of a comprehensive healthcare cost package to raise the age on all tobacco related products for every population in every corner of the United States to 21. Would that have a positive public health effect?

Dr. SCHUCHAT. Yes, we think that would.

Senator KAINE. Thank you very much. I yield.

Senator COLLINS [presiding]. Thank you, Senator Kaine. The Chairman has asked me to take over the hearing in his absence and as luck would have it, I am up next to do the questioning. And in any event, Mr. Zeller, and I am sorry that we are sort of blocked by the transcriber here, the dramatic increase that we are seeing in the use of e-cigarettes by our young people is threatening strides that we have made to reduce overall tobacco use.

You quoted in your written testimony a study that was done by the National Academy of Sciences, Engineering and Medicine that concludes that teens who experiment with an e-cigarette are more likely more likely to try conventional cigarettes compared to teens who had never used e-cigarettes. Hasn't the rationale that has been given for e-cigarettes is that it will help people stop smoking and yet here we have a study that clearly states that teens who began using e-cigarettes are more likely to start smoking conventional cigarettes. Could you comment on that?

Mr. ZELLER. Sure and thank you for the question, Senator. It is part of—called the public health balancing act. When we look at what's going on with kids, any kids' use of any of these products, whatever the trajectory is going to be, goes on the negative side of the ledger. But pulmonary delivery of nicotine in a properly regulated marketplace is something that could potentially benefit some currently addicted cigarette smokers but only if they completely switch to the electronic cigarette. And our job as regulators as we look at applications, as we look at what is going on in the marketplace, is to do this public health balancing act. The imperative from a public health perspective is to not allow another generation of kids to become addicted to nicotine.

Senator COLLINS. Well, that is exactly my fear not to mention the illnesses that we are seeing right now. Let me follow-up on a couple of other points that you made. In your written testimony, and again in your oral testimony, you said that it is important to remember that no e-cigarette product in the United States is on the market legally and that instead the FDA is exercising enforcement discretion. Given the harm that we are seeing and the high percentage of youths who are using it even in middle school and in high school, 27.5 percent you said today, why is the FDA exercising discretion?

Mr. ZELLER. As soon as we have a policy that we can come back to the Committee to talk about, we will be able to go into more detail about what the plans are. But your question is extremely well taken and we try to be as candid as possible about the state of the marketplace. From the day that we got regulatory authority over e-cigarettes starting in the summer of 2016, there was an exercise of enforcement discretion for the products currently on the market.

If there is an e-cigarette that is not on the market, they are subject to the premarket review or if a company tried to put in these cigarette onto the market after that August 2016 date, well, that is a violation of the law and we have taken enforcement action. So what we are talking about is the application of enforcement discretion to the products that were on the market as of that August 8th, 2016 cutoff date. And that is the policy that we are working on and

when it is finalized, we would be happy to come back to the Committee and go into detail on that.

Senator COLLINS. Given these very serious illnesses that we have seen in 49 states including Maine, why not ban refillable e-cigarettes? Wouldn't that help prevent situations where other teams are putting in oils or other dangerous substances like THC, or maybe they are not doing it, maybe criminals are doing it. But why allow them to be refillable?

Mr. ZELLER. Ultimately, for the products that have to come through a premarket review process, there is a court order deadline where whatever products remain on the market, these companies are going to have to file applications with the Agency by May of next year. What Senator Kaine was pressing on is well, where is the administration's policy now? What is the administration going to do about it? And what we are looking at is what are the steps that we can take to best protect kids. And it is two things. It is the alarming increase overall in kids use of e-cigarettes at the high school and middle school level and the increase in the popularity of flavored products.

Senator COLLINS. My time has expired, but I just want to say to the Doctor who is representing the CDC that Jennifer Rhoades in Maine public radio hosted an informational panel in September on this very issue. And it was very disturbing because what she shared was her finding that students said, everyone vapes, that the official statistics are lower than the reality. It is not something that is certain kind of kid does, it is everywhere.

Similarly Eileen King at the Maine School Management Association echoed that sentiment saying that vaping has exploded exponentially and that the adults, the teachers, the staff, the principle in general are ten steps behind the kids and even knowing that it is going on. So for the record, if you would respond since I am out of time, on what resources specifically are available to schools to highlight the dangers of vaping because until this latest spate of terrible illnesses, I believe based on students and teachers I have talked to, that they did not believe it was harmful and that is a real problem.

Dr. SCHUCHAT. We would be happy to submit for the record the family of materials because I agree with you. I hear exactly the same thing, that it is much worse than our statistics are telling us and moving very fast.

Senator COLLINS. Thank you.

Senator Smith.

Senator SMITH. Thank you, Senator Collins, and I am going to actually follow-up on the question that you just posed. I think it is a really important one. So in 2018, 1 in 4 11th graders in Minnesota reported using an e-cigarette in the last 30 days. That is a 54 percent increase from 2018. So the anxiety and worry that you hear from all of us on this panel are really reflected in that data. When I asked teachers in Minnesota what keeps them up at night, they point to two things. One, the growing concerns about the mental health of their students as well as the exponential rise in teen vaping. And I think that these things are related.

Here is a story. Claire Herring is a student at Hopkins High school in Minnetonka, Minnesota, and she turned to vaping, she

told us, to deal with her mental health concerns. And she says that this isn't uncommon amongst her peers. In her words, she said other students are "lost and they don't know what to do so they go for drugs and vaping is such an easy drug to get." And she is currently struggling to quit vaping.

Now, Claire is not one of these young people who thinks that vaping is nothing but flavored water. She understands that she is addicted. She understands that she has a problem. So to follow-up on Senator Collins' question, what is the CDC and the FDA doing to help teens like Claire who are already addicted and struggling to figure out how to help themselves? Dr. Schuchat, would you like to go?

Dr. SCHUCHAT. Yes. I can begin and it is a real challenge. We don't have FDA-approved cessation tools for young people and it may not be that the things that work in adults work as well in younger people. We think that behavioral therapy is part of the picture but that more research is needed. And you know, the best thing here is to be very aggressive with prevention because it is so hard for people once they start. And I think in terms of the mental health issues, we realize that the Nation is facing a family of challenges for young people. We have seen rises in suicide in young people and we really need to do more.

Senator SMITH. Yes. That is for sure.

Mr. ZELLER. A few points, Senator Smith. First, we are making a massive investment in paid media and getting the word out to kids in school. So as I said in my remarks, working with students against destructive decisions, we got really snarky posters placed in every single bathroom of every single public and private high school in the entire country last year.

That is where kids are going to Juul or to vape. We have also, working with scholastic, gotten much needed information into the hands of over a million middle school and high school administrators. But on the question of treatment, I agree with Dr. Schuchat, there is much more that needs to be done to help the teen that unfortunately has already become addicted and there are no FDA-approved drugs to treat nicotine addiction in teens.

We convened two very important public meetings earlier in the year. One was a formal hearing to bring in researchers in the pharmaceutical industry to raise the issue of what role can drug therapy and counseling play in helping teens. And then we had a more focused scientific workshop in the spring on the same issue. But there is a gap here that needs to be addressed and we are doing everything that we can to do that.

Senator SMITH. Where are teens getting this idea that this is harmless?

Mr. ZELLER. Apparently, it is the mindset in the word of mouth. And that is what we found from our research and that is why our paid advertising is heavily focused on nicotine addiction and health consequences to break that, what we call, cost-free mentality that kids have that it is just a water vapor and it is harmless. It is anything but.

Senator SMITH. This is sort of a—I am having a here we go again moment because I mean, of course that was a message that big tobacco put out on cigarettes for many, many decades.

I appreciate—I heard your testimony about the amount, about the dollars that you are spending on posters and bathrooms and with scholastic and all of that. And I mean certainly, that should be helpful. But my understanding is that Juul spent much, much, much, much more than that in the first 6 months of 2019 to advertise as well. So, I mean I am concerned that we are just outgunned on this. Dr. Schuchat, do you want to say something about that?

Dr. SCHUCHAT. Just to say that we believe there has been a lot of social media marketing, peer influencer marketing, under the radar kinds of ploy——

Senator SMITH. Right. That we can't even tally.

Dr. SCHUCHAT. Yes, and that young people really don't know or were even surprised that there is nicotine in these e-cigarettes. So I think there is a lot of work to do there because the wrong information has sort of set in, in terms of the understandings.

Senator SMITH. Right. I mean, it has been a long time since I have been a teenager but I remember clearly that I wasn't reading a lot of posters in the bathrooms. And I am not being dismissive of—I mean I am trying not to be dismissive but I am struggling to think about how we are going to combat this epidemic, as Senator Hassan said, that is going to have potentially lifelong challenges for these young people that are 15, 16, 17 and becoming addicted to this. And it is very disheartening. I mean I can only assume that it is the White House that is pulling back the September 11th rule because it goes against the data that the FDA and the CDC has about the safety of these products. So it is very concerning to me.

Senator COLLINS. Thank you.

Senator Murkowski, and I want to salute you and Senator Durbin for introducing your legislation, which I was pleased to co-sponsor.

Senator MURKOWSKI. Well, thank you. It has been a year's long now to deal with the flavors and so to be sitting here today and to feel like we have made some headway in reducing the availability of these flavors out on the market, but then to have very conflicting signals now coming out from the FDA and the White House on whether or not menthol and mint are included in this, I think, is unfortunately an escape.

When we are dealing with children and access to a highly addictive substance like nicotine for these underage individuals, the fact that we are even talking about giving that as a pass just I find mind-boggling and really very upsetting. You know, we have had some discussion about okay, is it that the kids really not appreciate that there is nicotine in these e-cigarettes? I asked, what is the level of labeling that is on e-cigs or on a vaping product? And I guess it is on the outside of the label. But if you are if you are that middle schooler and you are getting a refill in your cartridge or your pod, there is no label there. And again, the frustration here is you have kids who have seen advertised very clearly that these products are a cessation product.

If it can be used to get me off nicotine, then surely it can't be that bad for me even if there is nicotine in it. So when we are talking about consistent messages to kids, I think you got to be pretty upfront and pretty direct. This harms you. This will addict you.

This could ultimately kill you. I don't think we need to nuance the message here and I am just frustrated that we are still arguing over whether or not menthol or mint as a flavor in a nicotine based product is an attractant to kids or not an attractant.

If it makes it taste that much better, they are going to be attracted to it. Let me ask a couple questions here because the statistics that you provided us, Dr. Schuchat, 80 percent of those that have been tested for the lung illnesses, 80 percent of those had THC contained within, 70 percent had this vitamin E. I guess I am a little concerned that if we get to this point where the sense is that the investigation and the deaths, the illnesses are linked to THC with the vitamin E additive, that somehow or other then we say, okay, crisis over, we shouldn't be putting THC in a vaping product, and certainly shouldn't be putting vitamin E in a vaping product.

But beyond that, e-cigs and vaping products are not as bad and they are not going to kill you. Are you worried, and I guess this is directed to both of you, do you agree that even if the findings of the investigation do not implicate solely nicotine, that this should not be a distraction from the public health epidemic that we are facing which is this drastic rise in addiction to nicotine and e-cigarettes?

Dr. SCHUCHAT. Agree. There are two very disturbing epidemics going on. One is an outbreak of lung injury following e-cigarette or vaping product use that is pointing to THC containing cartridges in the vast majority. A second is this incredible skyrocketing rates of youth e-cigarette use and we know that the brain continues to develop until age 25 and nicotine is harmful for the developing brain. And the risk of these individuals being long-term addicted or going on to be addicted to other substances is very high. Two very, very disturbing emergencies.

Mr. ZELLER. Senator, we completely agree. It is really two separate issues. Kids should not be using any tobacco product, inhaling any of this stuff into their lungs. Everything that you are calling for in terms of the messaging directly to kids is exactly what we are doing in our paid advertising, talking directly to them about the presence of nicotine and that it can be addictive, talking direct directly to them about the presence of harmful compounds in the aerosol to try to break through what we call that cost-free mentality. Completely separate and apart from wherever the investigation takes us on the lung illnesses.

Senator MURKOWSKI. Just very quickly. Alaska is the one state where we have not seen illness and death. And that is good, no reported cases so far. In our state, retail marijuana is commercialized, it is tested by our state laboratories. So is the CDC providing any information to state regulatory bodies, whether it is Alaska or other states that have legalized on testing these products for these compounds that are a concern and then are there any barriers preventing Federal officials from working with our state marijuana labs on this topic?

Dr. SCHUCHAT. We are in close touch with the state health departments and their laboratories and are holding frequent calls and providing guidance. There are some challenges with shipment of specimens because of the scheduling of drugs.

Senator MURKOWSKI. Is that stopping any of the testing to your knowledge?

Dr. SCHUCHAT. I think it is just delaying it. I don't believe it is stopping it at this point, and Mr. Zeller can probably comment as well.

Mr. ZELLER. What I can add to that is, it is up to the states to send FDA the samples for testing. A number of states have. And when we complete our analysis, we then go back to each individual state with the results. So there really has been no issue in getting the samples to us and at least having us begin to do the chemistry work to be able to report back to them on a state-by-state basis. So it is like first in, first out. The first state that came to us is the first state that will get the results.

Senator MURKOWSKI. Thank you. Thank you, Madam Chair.

Senator COLLINS. Thank you.

Senator Rosen.

Senator ROSEN. Thank you. And I want to thank you for holding this timely hearing. I want to thank you for your efforts on this behalf. You know in Nevada we have had for lung related illnesses. Of course, greater than 2,000 cases across the Nation and 39 deaths. We must do something before these numbers continue to rise. But I want to build a little bit on what Senator Smith was talking about and talk about secondhand vaping.

When e-cigarettes first appeared on the market, it wasn't uncommon, like Senator Smith said, to refer to it just as water vapor in reference to the puffs released into the air when exhaling. So according to a number of experts, including researchers at Nevada's Desert Research Institute, when the user of a vaping product exhales, they are actually releasing nicotine and other particulate matter into the air. Of course this can be especially harmful to children, particularly if their parent or caregiver believes that there is no negative impact from secondhand vaping smoke.

Can you please elaborate on what you know about secondhand smoke in regards to vaping and what are your latest findings?

Dr. SCHUCHAT. The e-cigarette aerosol has a lot of different products or compounds in it. It can include heavy metals from the devices, things like lead, organic compounds, carcinogenic material, nicotine as you mentioned, and then what we call ultrafine particles that can be found deep in the lung. We are really at the beginning stage of understanding the aerosol effect in terms of secondhand smoke and there is a lot more that needs to be done.

Senator ROSEN. Do you think we could extrapolate from what we know from just regular cigarettes and the effects of second-hand smoke?

Dr. SCHUCHAT. There are aspects that can be extrapolated and others that can't be. The combustible tobacco has a lot more toxins and harmful substance in it. But I think what our view is that e-cigarette aerosols may have fewer harmful substances, but that doesn't mean they don't have harmful substances.

Senator ROSEN. Thank you.

Mr. ZELLER. The only thing that I would add to that is that this is a major area of investment in research by both agencies to better understand both what is in the aerosol and then what is being delivered to the bystanders. And as soon as we get the answers to

those questions, we will be in a better position to figure out what the potential harms are, what to say to consumers, and how to use that for regulatory policy purposes.

Senator ROSEN. Well, building on that, speaking about public health research, again researchers at Nevada's Desert Research Institute and University of Nevada Reno, they released information this summer about the aldehydes, right, such as formaldehyde, how they are absorbed into the lungs during vaping. These are chemicals widely known to cause cancer. So given that it appears that users of e-cigarettes assume they are inhaling some nicotine and flavored water, what is your understanding of the potential health risks of the aldehydes?

Dr. SCHUCHAT. In terms of the compounds, our principal message is that e-cigarettes should not be used by youth, young adults, or women who are pregnant, and the principal used really was intended to be for adults who are trying to quit smoking cigarettes. And that is where, the off-ramp conversation happens. The idea that they are harmless is wrong. The question about whether the aerosols and the various compounds cause harm directly or second hand is very much open.

Mr. ZELLER. I would add to that is that we have made formaldehyde the centerpiece of some of our paid advertising directly aimed at teens to make sure that they understand that the aerosol can contain formaldehyde which has been shown to be a cancer-causing agent.

Senator ROSEN. I suppose in the interest of time, my last question is, what in terms of funding for CDC or FDA, what do we need to help you with in funding or authorization to further expedite this research on vaping products, on the aldehydes, on secondhand smoke, on all of it?

Mr. ZELLER. I will go first. The administration's Fiscal Year 2020 request contained a request for $100 million additional for FDA for tobacco product regulation. And that is because with the existing dollars that we have had, we have either had to reallocate or reprioritized to do the right thing, whether it is compliance and enforcement, research, public education with the new and novel products like e-cigarettes. So the administration believes that there is a role for an increase in budget to expand our programmatic work in those three critical areas.

Senator ROSEN. Thank you.

Dr. SCHUCHAT. There have been House and Senate bills that talked about increasing CDC's tobacco budget by $40 million and the public health data issues, the Data Saves Lives, by $100 million per year. Those investments could help both the e-cigarette epidemic and help us with future threats like this one where we could get out of the gate a little quicker and not take so long to understand what is going on. Ideally to predict a threat instead of react slowly.

Senator ROSEN. Thank you. I yield back.

The CHAIRMAN [Presiding]. We have other Senators who would like to ask questions in a second round. And, let's see, Senator Cassidy, you may be next if you are ready, and then we will go to Senator Kaine. Senator Cassidy is always ready. The witnesses, you have been there for a long time as every—if you need a break for

any reason. I think we will probably go another not more than half hour so it would be my——

Mr. ZELLER. We are good.

The CHAIRMAN. Senator Cassidy.

Senator CASSIDY. Thank you both for attempting to address this issue. And I gather as—listening to Burr ask questions, he seemed to suggest that there has been some delay in determining what products might be responsible for this. But as I was reading about vitamin E acetate, it has oil in it, and I remember from medical school if you inhale oil, you do a lot of damage to your lungs. And that was mineral oil you were swallowing to clean out your bowels not a heated solution dispersing broadly. Do we really need to do a lot of study to tell people not to heat up oil and to inhale it into their lungs?

Dr. SCHUCHAT. We don't need to do a lot of studies for that question but I think there are many questions that remain. We don't know that there are other substances that are being either——

Senator CASSIDY. Are you imagining that it is non-oil-based?

Dr. SCHUCHAT. There may be non-oil based. There has been a report of cobalt for instance from the device. So we think there is potentially a variety of products but I agree with you that vitamin E acetate, this oil in products that are being heated and inhaled is bad news.

Senator CASSIDY. Now, I think I remember reading although I was walking, couldn't find the article, that the British have really talented the vape to be, the electronic cigarette, to be a risk mitigation. I think I see something from CDC or I think from CDC of the risk mitigation aspect of this. Yes, you are getting nicotine, but you are not getting all these carcinogens that are associated with cigarette smoking.

Assume that there is two aspects to this consideration, or at least two. First, the flavored cigarettes which induce young people to smoke cigarettes, become addicted, and remain as addicts for the rest of their life. Terrible, shouldn't happen. The second is what is the risk benefit ratio of using something which has potential for risk mitigation, reducing the risk of somebody smoking carcinogenic cigarettes for something which is less, balanced against the public health risk of people misusing them and inhaling cobalt and oil and whatever else. Would you all agree with that assessment?

Dr. SCHUCHAT. Just, briefly. The UK situation is quite different. They have a lower content of nicotine in the e-cigarettes that are distributed there and they have a very aggressive sort of graphic label type of approach to warn the public. And they don't seem to have the youth epidemic that we are experiencing.

Senator CASSIDY. But that goes back to the youth epidemic not to the fact that it is risk mitigation.

Dr. SCHUCHAT. Right. They are really focusing the distribution of this lower nicotine content, e-cigarette, on adult cessation, but I think Mr. Zeller had more to say.

Mr. ZELLER. I agree with you Senator. It is a balancing act and Congress wrote that balancing act into the law with mandatory considerations. As we are looking at products on an application by application basis, we have to account for impact on initiation. Any initiation by kids goes on the negative side of the ledger. But to

your point, what potential beneficial role can any of these alternative technologies play and that would go on the positive side of the ledger, but what we know with e-cigarettes is that the benefit comes only if you completely switch from cigarettes to e-cigarettes. The overwhelming majority of adults who are using e-cigarettes continue to smoke at least some conventional combustible cigarettes.

Senator CASSIDY. It doesn't make sense to me, I am just asking I am not arguing, that you have to make a complete transition because with cigarette smoking, I remember there is the 20 pack per day—again, I am having to remember this from school but one pack per day for 20 years however you get there. A half a pack times 40 years, two packs times 10 years, one pack times 20, but there is a threshold effect above which the effects of cigarette smoking and your risk for cancer escalates. So if we minimize that, it seems as if that would be risk mitigation, even if someone continues a smoke two real cigarettes a day.

Mr. ZELLER. Well, I will defer to Dr. Schuchat and others on what the science says about reduction. What we know from the available epidemiological data is the overwhelming majority of e-cigarette users continue to smoke cigarettes.

Senator CASSIDY. I get that but that is not my point.

Mr. ZELLER. I think that the science shows that whatever the potential public health benefit would be, would be lessened and reduced in the absence of——

Senator CASSIDY. I accept that as well but not entirely lost. Again, if there is a threshold effect above a certain point, your risk from cigarette disease increases dramatically, anything you do to substantially decrease that usage and therefore keep it below that threshold is beneficial.

Mr. ZELLER. I am unaware of the science that shows that we know the answer on a cigarettes per day basis. It is clear that duration of use, the length of time that you smoke, whatever the number of cigarettes, is definitely related to your risk of disease.

Senator CASSIDY. I am out of time. I thank you both. I yield back.

The CHAIRMAN. Senator Kaine.

Senator KAINE. Thank you, Mr. Chairman. Two items, data modernization and then the research on smoking cessation just to follow-up on the discussion that you're just having with Senator Cassidy. Maybe first, Dr. Schuchat, if you would, what is the current status of research and I know a number—much of it is international—but what is the current status of research on the smoking cessation effect of e-cigarette use among adults?

Dr. SCHUCHAT. Yes. The research so far is mixed. There have been three randomized control trials with somewhat different results. The most recent trial from the UK did find some benefit from e-cigarette use in adult cessation. It was coupled with behavioral counseling which we know is important and it was an earlier generation e-cigarette product.

Senator KAINE. But it was a product that was compliant with the UK's rules about nicotine. And nicotine threshold in the UK is about a third of what the nicotine would be in the standard Juul that is available commercially, correct?

Dr. SCHUCHAT. Yes. That is right.

Senator KAINE. But that one shows some positive effect if you couple it with behavioral therapy to try to reduce smoking. What about other studies?

Dr. SCHUCHAT. Well, the other studies didn't find the same effect. And the important things I don't believe there have been studies with the current generation of e-cigarette products that have the nicotine salts, which allows you to—overcomes the harshness and allows for a much higher dose exposure. And we do think that higher dose exposure makes addiction more likely.

Senator KAINE. Dr. Schuchat, I was out to vote. I don't—did you talk about nicotine salts in the public testimony already?

Dr. SCHUCHAT. I don't believe so.

Senator KAINE. Nicotine salts are a technological advance that Juul has put in place that takes the harshness of nicotine and by altering its pH balance reduces the harshness. And that together with flavoring is something that is an attractor to people who are using the product. Isn't that correct?

Dr. SCHUCHAT. Yes. That is right.

Senator KAINE. Mr. Zeller, do you have anything else on the science of smoking cessation studies, the current state of affairs?

Mr. ZELLER. Two points. Important to emphasize that much of what has been published is on earlier generation products so this remains a moving target, but the official position of the U.S. Preventive Services Task Force is that e-cigarettes are not recognized as an effective cessation aid. And if there are cigarette smokers who are concerned about their health and interested in quitting, what they should be looking at is FDA approved by the prescription or over-the-counter drugs coupled with counseling of any kind, because if you couple the drug with the counseling you can double your chances of success.

Senator KAINE. FDA has approved and number, six or seven if I remember correctly, of smoking cessation technologies that can be used——

Mr. ZELLER. Yes, including products that don't even require prescription. Nicotine gum, nicotine patches, nicotine lozenges available in pharmacies.

Senator KAINE. Great. Thank you. Next issue, data modernization. The Lowering Health Care Costs Act that the Committee voted on a couple of months back included a piece of legislation that I introduced with Senator Isakson and King to modernize public health data infrastructure. The name of the piece of legislation was the Saving Lives Through Better Data Act and it included Section 405 of the Lowering Health Care Costs Act along with some other items dealing with data. If you could, and I just talked to Senator Isakson about this and he wanted me to ask about this, why is better public health data important to dealing with an epidemic like youth e-cigarette use?

Dr. SCHUCHAT. You can see how quickly the behaviors changed. When a new market entered the distribution, this rapid skyrocketing use of e-cigarettes. Public health has been very lead-footed both with the epidemic of e-cigarette use and with this lung injury. The public health departments are getting faxes and CDs from hospitals of medical records having to enter data multiple

times. The systems between electronic medical records and the public health are not interoperable yet.

The CDC is trying to integrate information from a variety of different systems. We think we can get modernization of public health that will give us more efficient use of people's time, more effective recognition of problems, and ideally get a public health workforce that can be predicting instead of reacting to health threats.

Senator KAINE. Mr. Zeller, would you add anything to that?

Mr. ZELLER. Yes. From a regulatory standpoint, we are only as good as the available regulatory science. And one of our great challenges if not frustrations is that the research isn't rapid response enough. So in our grants, in our contracts, we try to build in a rapid response mechanism as the products continue to change. I will just say that it remains a work in progress.

Senator KAINE. Thank you. Mr. Chairman, if I could, I would like to introduce for the record a letter from the Council on State and Territorial Epidemiologists focusing attention upon the data improvement aspects of the Lowering Health Care Costs Act and supporting those aspects of the bill.

The CHAIRMAN. Thank you, Senator Kaine. Senator Murray and I hope the Lower Health Care Costs Act becomes law with your provision in it. We are working to do that.

Senator Romney.

Senator ROMNEY. Thank you, Mr. Chairman and Ranking Member for holding this hearing, and thanks to our two witnesses for being here and testifying today. As you know, this is an issue that the entire Nation cares about. In particular in my State of Utah, the rate of vaping illness is of particular concern because it is six times the national average. And we have already lost one of our citizens to this vaping related illness. There are two obviously serious and somewhat related issues, one is of course the people who are subject to these terrible illnesses associated with vaping and the other is the epidemic of addiction among our young people.

How did we get here? What did we get wrong? Because it is hard for me to imagine that there is a logical setting where we have what, over 5 million young people now addicted to nicotine. At the same time we are doing everything we can to stop smoking and we have been quite successful in reducing smoking and yet massive increase in addiction. And somehow, we don't do anything about it.

What did we do wrong? What should we do differently? Is it your issue or is it our fault, by the way? I know it is tempting for me to join in blaming you all for not doing something to stop what happened. But should we have acted? Is there something we should have done or need to do now so that this doesn't continue to happen or happen in another way at another time?

Mr. ZELLER. I will start from the FDA and the regulatory perspective and then ask Dr. Schuchat to add from the CDC perspective. As I said in my oral remarks, we tried long before the epidemic of kids use of e-cigarettes and long before the outbreak of lung injuries to regulate e-cigarettes as unapproved combination drug device products, and we were sued, and we lost. And what the court said is in the absence of an e-cigarette product basically making a drug claim, the only authority that FDA had to regulate e-

cigarettes, because the nicotine in e-cigarettes is derived from tobacco, is under the tobacco authorities, the Tobacco Control Act.

We went through a rulemaking process as the statute requires and didn't begin to have regulatory authority over e-cigarettes until the summer of 2016, just a little over three years ago. So you could say that some of the things that had already been set in motion that led to what we all agree today is an epidemic level of kids use of e-cigarettes was occurring at a time when we were calling the marketplace for e-cigarettes before we got that regulatory authority, the Wild Wild West.

There was absolutely no regulation. Since we have had the regulatory authority, we have worked very hard to use all the tools that we have from compliance and enforcement tools to massive investment in public education and research to get answers to all the important questions that the Committee is asking about just the basic product themselves and what is going on with kids.

I would say it is a confluence of contributing factors, industry behavior at a time when there was no Federal regulation of these products, industry behavior that continued after we got that authority and we have tried to use our enforcement tools to go after the bad actors, and the mindset of kids. They walk around thinking that these are harmless products. A whole bunch of kids don't even know that nicotine is present. So I would say that it is a confluence of industry behavior and the mindset of kids and as regulators we are trying to use all the tools that we have to respond and to combat that.

Senator ROMNEY. Thank you.

Dr. SCHUCHAT. I agree but I would say there are three key factors that led us to where we are, that led to this skyrocketing of teenage use of e-cigarettes. The first is advertising and it didn't show up the way we are used to on Billboards or TV ads. It was social media, youth influencers, under the radar for us adults that really influenced kids to think it was cool to do this.

The second thing was flavors, candy, fruit, things that were not at all in young people's minds associated with cigarettes or nicotine. And then the third is nicotine, one of the most addictive substances there is and with the newer generation products, the nicotine salts, the harshness that nicotine or tobacco products have was gone, and so the addiction could really take hold. Not addressing those three factors led us to where we are.

Senator ROMNEY. Thank you. I would note that in the words of the cartoon Pogo, we met the enemy and the enemy is us. And I am referring in some respects to those of us on this side of the room, which is we need to take action to provide authority for you to be able to regulate effectively these products. And at this stage as I understand, Senator Murkowski has put in place legislation or proposed legislation over a year ago to restrict flavors and yet we don't act. We talk about this epidemic among young people and wonder why you all haven't done something about flavors, but why haven't we done something about flavors.

Senator Berkeley and I put together a piece of legislation that does four things. One, it makes these flavors illegal. Number two, it insists on close tanks, a closed system as opposed to one that people can add THC and other products to. Three, it puts a lot

more money into advertising on social media and other media sources to go to kids.

Finally, it pays for that advertising by putting an excise tax on nicotine just like the excise taxes on nicotine in cigarettes. If that legislation were to pass, my presumption is we would have a dramatic impact on reducing the number of kids that get addicted to nicotine. Do you agree? And a one-word answer is all you have got time for.

Mr. ZELLER. All I can say from the FDA perspective is we would be happy to work with you on that. I think that there is evidence based for the positive public health impact of the elements that you are describing there. We would be happy to work with you.

Dr. SCHUCHAT. Yes, I agree. And just to say that we think that tobacco control needs to be comprehensive, that Federal, state, and local efforts are needed, and that there is a history here of whack a mole that when we take care of a set of issues other issues emerge. So investment in monitoring that is modern so we can be on top of new threats that emerge.

The CHAIRMAN. Thank you, Senator Romney.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman, and thank you for allowing a second round of questions. I had intended to ask about any expertise that had been developed relating to helping young people quit smoking, quit vaping, cease using nicotine. That has already been asked so I want to kind of explore a little bit further. If we are using adults perhaps as our best way of guessing, what these folks under 18 will experience, what percentage of the 5 million youths who are vaping nicotine products will become addicted to nicotine?

Dr. SCHUCHAT. I don't actually know that statistic. I don't know if you do?

Mr. ZELLER. We don't know that but there is an alarming trend that could be putting kids on the pathway to addiction from the annual National Youth Tobacco Survey results, and that is of the current e-cigarette users who are middle school or high school students, how many of them are so-called frequent users?

Frequent uses defined as, did you use on 20 or more of the past 30 days? And unfortunately, the percentage of current e-cigarette users in middle school and high school who are frequent users is rising. It is now a total of 1.6 million middle and high school kids in the 2019 NYTS data are frequent users, and almost 1 million of those 1.6 million used e-cigarettes every single one of those days.

Senator BALDWIN. Okay, again using adults as our best source of information, our experience with adults, an adult who is trying to stop using nicotine, what information do we have about how often or how many times they try before they actually successfully cease using?

Mr. ZELLER. I will also from the FDA perspective because our center for drugs actually puts those products on the market as smoking cessation aids, but on the tobacco side, we also have had a paid media campaign called Every Try Counts where we are putting positive quit messages into gas stations and convenience stores because 96 percent of all the cigarettes that are sold in the United States are sold in gas stations and convenience stores. And what

we are trying to do is to get the health concerned smoker who made a quit attempt in the past 12 months but was unsuccessful to try again.

Typically a smoker has to try, 10 or more times before they will ultimately succeed. And the real world Effectiveness rate of the FDA approved over-the-counter products, at least the nicotine gum, nicotine patches, nicotine lozenge, the real world effectiveness rate of these products is low. It is in the single digits.

We need to get more smokers to be serious about making the quit attempt and we need to get the word out to them that it is often a matter of trying and trying again, and as Dr. Schuchat said earlier, then combining whatever drug you use, FDA approved drug that you use, with counseling of any kind, online, in person, group counseling because that can more than double your chances of succeeding.

Senator BALDWIN. It sounds like those should be the posters that are up in the middle school and high school bathrooms.

Mr. ZELLER. We need to know what will work with kids and that is what we are trying to get to the bottom of.

Senator BALDWIN. But we don't have a lot of time, right? We can't do a peer-reviewed study that takes, however long. We need to offer services to these children now. So support groups can be in school and that sort of thing.

Mr. ZELLER. We are. So there are online—so putting aside whether there is FDA-approved medications, there are a number of Government and online resources. And so through our youth prevention efforts, we have more than doubled the number of inquiries to an NCI website where kids can go for help in getting more information about quitting. But we still need to do more work on what are the products that we know will actually help them quit.

Senator BALDWIN. I am going to submit some additional questions for the record because the answers just beg other questions, but one that I will submit for the record, Dr. Schuchat, is you said in your testimony that the ongoing investigation into the lung injury presents a number of challenges to both public health agencies and health care providers, and I would be interested in getting more detailed information about what the CDC is sharing with state health departments and providers on best practices for identifying and treating the illness.

Dr. SCHUCHAT. I would be happy to submit that.

Senator BALDWIN. Thank you.

The CHAIRMAN. Thank you, Senator Baldwin.

Senator Murray.

Senator MURRAY. Thank you. Mr. Zeller, I want to go back to you because I really am deeply troubled by the FDA's failure to complete key actions to protect the public health. We talked about the delay of the premarket review requirements for e-cigarettes and the flavor policy but the Agency has dragged its feet on many other policies, graphic warning labels that Senator Enzi offered in the Tobacco Control Act, taking actual action on menthol cigarettes, implementing track and trace, a mandate that would actually deter illicit trade and bolster enforcement of key requirements.

When this Committee worked to pass the law more than a decade ago it ensured the FDA had full authority to fundamentally re-

make the tobacco market. Can you tell us why these and other important provisions from the Tobacco Control Act have been so significantly delayed or not even started?

Mr. ZELLER. I think that a number of the items that you listed are things that we have been working on and that we share your concern about how much of a priority that they are. We have a completely stood up center with active, programmatic efforts in the major and most important programmatic areas, compliance and enforcement, public education, product review, regulatory science research, and then all the operations and management that goes with all of that. And we are ready for the applications for these products to come in. I think that the examples that you gave are important examples and happy to work with you and your staff to give you status reports on where each of those stand.

Senator MURRAY. I appreciate that. But I just have to say, Mr. Chairman, first of all, thank you for having this hearing and thank you to both of you for coming and testifying but it just seems to me we need swift, bold, quick action on addressing these issues. So I am going to keep pressing the Trump administration which you have told us we have to talk to, including through the Acting FDA Commissioner and our new nominee should he be confirmed as well.

We need to stop these delays and we need to deliver strong steps that have already been promised and I think that is critically important for this Committee to go really forcefully on. And I of course will continue to work with our colleagues on both sides of the aisle to do what we can to address this really critical crisis. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murray and I would emphasize to the witnesses and to the public, this is another one of our bipartisan hearings and I think you can see in the questions and attendance today the amount of interest in it. Let me follow-up with what Senator Romney and Senator Murray—Senator Romney asked, what authority do you needed that you didn't have? Senator Murray talked about authority.

Ms. Schuchat talked about three studies, I believe, the most promising of which in Great Britain showed was due to a lower level of nicotine in the e-cigarette. Do you agree, Mr. Zeller, that study suggested that a lower level of nicotine in the e-cigarette would be more effective in helping people to stop smoking?

Mr. ZELLER. I am not familiar with that study and I can't make that finding that a lower level of nicotine in the e-cigarettes in the UK, given all the other factors that are present there, is a direct contributing factor to what is going on.

The CHAIRMAN. Ms. Schuchat, did I characterize that correctly?

Dr. SCHUCHAT. Yes. Let me clarify. It was a randomized control trial comparing 20 milligrams per milliliter e-cigarette with control. And so it wasn't showing that a lower was better than a higher, the products they were using were not as high nicotine content as the products that are in the market in the U.S.

The CHAIRMAN. Well, in terms of authority, let me ask you, Mr. Zeller, do does the FDA have the authority to require lower nicotine levels in e-cigarettes?

Mr. ZELLER. Armed with the science to support it, yes.

The CHAIRMAN. Yes. Does the FDA have the authority to require the kind of closed cartridge or tamper-proof cartridge that Senator Romney talked about in his legislation?

Mr. ZELLER. Yes. If the evidence was there to support it, we could use something called the product standard authority to put those kinds of provisions in place in the marketplace.

The CHAIRMAN. Does the FDA have the authority to require a warning label to be on the device itself?

Mr. ZELLER. We already have done that. There is a mandatory nicotine addiction warning on all these products.

The CHAIRMAN. Well, let's see. On this, you can put a warning label on this?

Mr. ZELLER. It would be on the package that product was sold in.

The CHAIRMAN. Well, that is not what we are talking about. Have you got the authority to put a warning label on this itself?

Mr. ZELLER. That, I will need to get back to you for the record for something that would be inside the package. But there is a mandatory nicotine addiction warning on the labeling and the packaging for that product.

The CHAIRMAN. The problem you run into was the First Amendment problem with your graphic?

Mr. ZELLER. That is correct.

The CHAIRMAN. Graphic, which is different in the UK. They don't have a First Amendment if I remember, right?

Mr. ZELLER. Correct.

The CHAIRMAN. Or much of one. Do you have the authority to regulate the size of these devices?

Mr. ZELLER. What do you mean by size?

The CHAIRMAN. Well, some of them are this big, some of them are small, some—we have got a chart here with a bunch of them on——

Mr. ZELLER. That, I will need to consult with the Agency and get back to you on. It is possible that could be something under our products end authority, but I don't know and I don't want to misspeak so I will get back to you.

The CHAIRMAN. Do you have the authority to regulate or ban certain flavors in e-cigarettes?

Mr. ZELLER. Yes, we do.

The CHAIRMAN. Do you have the authority to spend more of the user fees that you get from the tobacco industry on finding more effective ways to encourage young people not to use e-cigarettes?

Mr. ZELLER. We have done that. We have reallocated a sizable portion——

The CHAIRMAN. But you don't need us to pass a law for you to do that, right?

Mr. ZELLER. No. But my point is that we have already done that on the public education side.

The CHAIRMAN. I know you—but apparently it doesn't work because we have got 1 out of 4 high school students vaping.

Mr. ZELLER. I tried to make it clear that we have more work to do. But if the question is do, we know have——

The CHAIRMAN. But what I am trying to make it clear is, do you have the authority within that more than $5 billion you have col-

lected over the last 10 years to spend more of it on more effective ways to deal with young people?

Mr. ZELLER. Yes, we do.

The CHAIRMAN. If I go through that level, while you want to get back to me on a couple of them, you appear to have the authority to lower nicotine level requirements to deal with close—to require closed tamper-proof cartridges. You may have the authority to put a label directly on a device or to regulate the size. You do have the authority to regulate flavors and you could spend more than you are currently spending, although you would have to spend less on something else, on focusing on more effective ways for young people. So there is a lot you could do and you could move the proposed regulations into final status more quickly, correct?

Mr. ZELLER. Yes. Yes, sir, and two points. First, finalizing those proposed rules is a huge priority. Second, how to use the broad authority that we have to address many of the product characteristics that you asked about is something that we are actively considering internally. And that is how to use the product standard authority which requires going through a rulemaking process to address various issues related to these.

The CHAIRMAN. Well, I think you heard today some differences of opinion about attitudes toward tobacco, some, not much but some. I don't think you heard any about the importance of two things, one is getting to the bottom of this mysterious illness that you and the CDC are working on as quickly as we can. And two, dealing with the epidemic of young Americans, high school students who are vaping.

We hope that the legislation that Senator Kaine and Senator McConnell, Senator Murray and I and others have, as part of our Lowering Health Care Costs Act, which passes Committee 20 to 3, will become law and move the age for the purchase of tobacco products up to 21. That should help. But in the meantime, it looks to me like you have a lot of authority to do more about e-cigarettes, especially for young people and that there is plenty of support on this Committee for you to do that.

I want to thank both of you for coming today and for your professionalism. And there are a few follow-up questions as Senators had, particularly about the amount of spending that FDA does for young—on trying to persuade young people not to use vaping. The hearing record will remain open for 10 days. Members may submit additional information for the record within that time if they would like.

The CHAIRMAN. We will meet again on Wednesday in this Committee, on November 20th, for hearing on the nomination of Dr. Stephen Hahn to serve as Commissioner of Food and Drugs. My guess is this subject will come up then again. Thank you for being here today.

The Committee will stand adjourned.

ADDITIONAL MATERIAL

E-Cigarette Use Among Youth in the United States, 2019

Research

JAMA | Original Investigation

e-Cigarette Use Among Youth in the United States, 2019

Karen A. Cullen, PhD; Andrea S. Gentzke, PhD; Michael D. Sawdey, PhD; Joanne T. Chang, PhD; Gabriella M. Anic, PhD; Teresa W. Wang, PhD; MeLisa R. Creamer, PhD; Ahmed Jamal, MBBS; Bridget K. Ambrose, PhD; Brian A. King, PhD

IMPORTANCE The prevalence of e-cigarette use among US youth increased from 2011 to 2018. Continued monitoring of the prevalence of e-cigarette and other tobacco product use among youth is important to inform public health policy, planning, and regulatory efforts.

OBJECTIVE To estimate the prevalence of e-cigarette use among US high school and middle school students in 2019 including frequency of use, brands used, and use of flavored products.

DESIGN, SETTING, AND PARTICIPANTS Cross-sectional analyses of a school-based nationally representative sample of 19 018 US students in grades 6 to 12 participating in the 2019 National Youth Tobacco Survey. The survey was conducted from February 15, 2019, to May 24, 2019.

MAIN OUTCOMES AND MEASURES Self-reported current (past 30-day) e-cigarette use estimates among high school and middle school students; frequent use (≥20 days in the past 30 days) and usual e-cigarette brand among current e-cigarette users; and use of flavored e-cigarettes and flavor types among current exclusive e-cigarette users (no use of other tobacco products) by school level and usual brand. Prevalence estimates were weighted to account for the complex sampling design.

RESULTS The survey included 10 097 high school students (mean [SD] age, 16.1 [3.0] years; 47.5% female) and 8837 middle school students (mean [SD] age, 12.7 [2.8] years; 48.7% female). The response rate was 66.3%. An estimated 27.5% (95% CI, 25.3%-29.7%) of high school students and 10.5% (95% CI, 9.4%-11.8%) of middle school students reported current e-cigarette use. Among current e-cigarette users, an estimated 34.2% (95% CI, 31.2%-37.3%) of high school students and 18.0% (95% CI, 15.2%-21.2%) of middle school students reported frequent use, and an estimated 63.6% (95% CI, 59.3%-67.8%) of high school students and 65.4% (95% CI, 60.6%-69.9%) of middle school students reported exclusive use of e-cigarettes. Among current e-cigarette users, an estimated 59.1% (95% CI, 54.8%-63.2%) of high school students and 54.1% (95% CI, 49.1%-59.0%) of middle school students reported JUUL as their usual e-cigarette brand in the past 30 days; among current e-cigarette users, 13.8% (95% CI, 12.0%-15.9%) of high school students and 16.8% (95% CI, 13.6%-20.7%) of middle school students reported not having a usual e-cigarette brand. Among current exclusive e-cigarette users, an estimated 72.2% (95% CI, 69.1%-75.1%) of high school students and 59.2% (95% CI, 54.8%-63.4%) of middle school students used flavored e-cigarettes, with fruit, menthol or mint, and candy, desserts, or other sweets being the most commonly reported flavors.

CONCLUSIONS AND RELEVANCE In 2019, the prevalence of self-reported e-cigarette use was high among high school and middle school students, with many current e-cigarette users reporting frequent use and most of the exclusive e-cigarette users reporting use of flavored e-cigarettes.

Related article

Supplemental content

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Most tobacco product use is initiated during youth and young adulthood.[1] In 2018, an estimated 4.0 million high school students and 840 000 middle school students were current (past 30-day) tobacco product users.[2,3] Since 2014, e-cigarettes have been the most commonly used tobacco product among youth.[2] The popularity of e-cigarettes shaped like USB flash drives and other similar devices likely has contributed to youth uptake; these devices can be used discreetly, may have a high nicotine content, and come in flavors that appeal to youth.[4] Most e-cigarettes contain nicotine, and nicotine exposure during adolescence can harm the developing brain, which continues to develop until about age 25 years.[5,6] Nicotine exposure during adolescence can affect learning, memory, and attention[5,6] and can increase risk for future addiction to other drugs.[1,5]

During 2011-2015, current e-cigarette use among US high school students increased from 1.5% to 16.0%, before declining to 11.3% in 2016 and remaining unchanged at 11.7% in 2017.[7] However, a substantial increase in current e-cigarette use by middle and high school students occurred during 2017-2018,[2,3] leading the Food and Drug Administration Commissioner and the US Surgeon General to declare youth e-cigarette use an epidemic in 2018.[6,8] A 2018 Surgeon General's Advisory called for aggressive steps to reduce e-cigarette use among youth, including evidence-based population-level strategies.[6,9,10] The advisory reinforced the importance of continued surveillance of e-cigarette use among youth, which is critical to inform the development, implementation, and sustainment of such strategies.[6]

However, whether the recent increase in e-cigarette use continued into 2019 is unknown. The objectives of this study were to (1) assess the most recent prevalence of self-reported current (past 30-day) e-cigarette use among US high school and middle school students; (2) describe use characteristics among current e-cigarette users; and (3) describe flavored e-cigarette use among current exclusive e-cigarette users.

Key Points

Question What is the estimated prevalence of the current (past 30-day) use of e-cigarettes among US high school and middle school students in 2019?

Findings In this cross-sectional survey conducted in 2019 that included 19 018 participants, the prevalence of self-reported current e-cigarette use was 27.5% among high school students and 10.5% among middle school students.

Meaning In 2019, the prevalence of self-reported current e-cigarette use was high among US high school and middle school students.

Methods

Data Source

The National Youth Tobacco Survey (NYTS) study protocol was approved by the institutional review board of the US Centers for Disease Control and Prevention (CDC). Participating schools determined whether parental consent would be received actively, whereby parents provided written permission allowing their child to participate in the survey, or passively, whereby parents signed and returned the permission form only if they did not want their child to participate in the survey. Parental consent and respondent assent were obtained for all participants. The NYTS is a cross-sectional, school-based, self-administered questionnaire that has been administered to US high school (grades 9-12) and middle school (grades 6-8) students since 1999.[11] A 3-stage cluster sampling procedure, including primary sampling units, schools, and classrooms within schools, is used to generate a nationally representative sample of US students attending public and private schools in grades 6 through 12. Detailed information about the annual survey is available elsewhere.[11] Race and ethnicity were separately assessed by self-report with fixed category response options. Students could select 1 or more of the following categories for race: American Indian or Alaska Native, Asian, black or African American, Native Hawaiian or other Pacific Islander, or white. Students could select whether they were Hispanic, Latino, Latina, or of Spanish origin.

During 1999-2018, the survey was conducted using a paper-and-pencil questionnaire. The 2019 survey data were collected solely using an electronic mode of survey administration including skip patterns and product images following the implementation of an electronic pilot survey administration in 2018.[12] Data collection for the 2019 survey occurred from February 15, 2019, to May 24, 2019. Data were collected offline using a survey application that was loaded onto an electronic tablet.

Students absent on the day of survey administration could participate using a web-based version of the questionnaire, which was programmed to mimic the tablet-based application. Skip patterns were programmed in the 2019 questionnaire to reduce respondent burden; respondents were not asked about tobacco-specific use behaviors if they did not report using each respective tobacco product. Each product-specific section began with a product description and included nonbranded example images. Brand examples also were included in the product description text for select tobacco products, which were identified as top brands based on dollar sales for the 52 weeks ending on April 21, 2018, using Nielsen Scantrack data[13] for total US convenience stores and all outlets combined. JUUL was added as a brand example to the e-cigarette section description in 2019; all other brand examples in 2019 were included in the previous survey year. The questions used in this study are listed in the eAppendix in the Supplement.

Measures

Current use of e-cigarettes was defined as use on 1 or more days of the past 30 days. Current exclusive e-cigarette users were those who reported past 30-day use of e-cigarettes but no other tobacco product. To be consistent with previous literature on frequent use,[6] among current e-cigarette users, frequency of use of e-cigarettes was dichotomized as use on 20 or more days or fewer than 20 days during the past 30 days. Measures of current use of any tobacco product and of cigarettes were

included to provide context for the current e-cigarette use estimates. Current "any tobacco product use" was defined as use of 1 or more tobacco products (cigarettes, e-cigarettes, cigars [cigars/cigarillos/little cigars], smokeless tobacco [chewing tobacco, snuff, dip, snus, and dissolvable tobacco], hookah tobacco, pipe tobacco, and bidis) on 1 or more days of the past 30 days. Current use of cigarettes was defined as use on 1 or more days of the past 30 days.

Usual brand use was first assessed in 2019 among current e-cigarette users by the question, "During the past 30 days, what brand of e-cigarettes did you usually use?" Respondents could select JUUL, blu, Logic, MarkTen, NJOY, Vuse, some other brand not listed here, or indicated that they did not have a usual brand of e-cigarette. Those who selected "Some other brand not listed here" could provide a write-in response; write-in responses were recoded into valid responses (2 additional brands, SMOK and Suorin, are reported based on the write-in responses).

Use of flavored e-cigarettes was determined by the response to the question, "Which of the following tobacco products that you used in the past 30 days were flavored to taste like menthol (mint), alcohol (wine, cognac), candy, fruit, chocolate, or other sweets?" Participants could select from a list of options to indicate the flavored tobacco product(s) they had used. Current e-cigarette users who selected e-cigarettes from the list of tobacco products were categorized as flavored e-cigarette users; current e-cigarette users who indicated "I did not use any flavored tobacco products in the past 30 days" were categorized as unflavored e-cigarette users, and those who skipped this question were categorized as unknown flavored e-cigarette users. Beginning in 2016, respondents who indicated they used 1 or more flavored tobacco products were asked, "What flavors of tobacco products have you used in the past 30 days?" Participants could select 1 or more of the following responses: menthol or mint, clove or spice, fruit, chocolate, alcoholic drink (such as wine, cognac, margarita, or other cocktails), candy, desserts, or other sweets, or some other flavor not listed here. Those who indicated "some other flavor not listed here" could specify with a write-in response.

Statistical Analysis

Statistical analyses were conducted using SAS-callable SUDAAN (SUDAAN version 11.0.3, Research Triangle Institute) to account for the complex sampling design. A weighting factor was applied to each student record to adjust for nonresponse and for varying probabilities of selection; weights were adjusted to ensure that the weighted proportions of students in each grade matched national population estimates. The weight adjustment for student nonresponse was made by sex and grade within schools so that the sum of student weights over participating students within a school matched the total enrollment by grade and sex in the school during data collection. At the school level, nonresponse adjustments used school type (public, nonpublic), National Center for Educational Statistics locale indicator, and school-level poverty status. Weighted prevalence estimates and 95% CIs for current use of any tobacco product, cigarettes, and e-cigarettes were assessed among high school and middle school students separately. Estimates are considered statistically unreliable and are suppressed if the unweighted denominator is less than 50 or the relative standard error is greater than 30%.

Among current e-cigarette users in high school and middle school, frequency of e-cigarette use (<20 days vs ≥20 days; daily use on all 30 days) was reported. Usual brand of e-cigarette used in the past 30 days was reported among current e-cigarette users only. Analyses of past 30-day flavored e-cigarette use, and specific flavor types used, were restricted to current exclusive e-cigarette users to reflect flavor types used in e-cigarettes only. Supplemental analyses compared characteristics of JUUL users with those who reported use of another brand or indicated no usual brand.

In 2018, a pilot survey of the NYTS was conducted using 2 electronic versions, one programmed to align with the paper-based survey and the other to take advantage of electronic administration, including programmed skip patterns and tobacco product images[12]; minimal differences in tobacco product use estimates were observed between the 2 electronic pilot survey versions in 2018.[12] However, due to various questionnaire improvements and the change in survey administration mode in 2019, statistical testing was not conducted for changes in tobacco product use behaviors (prevalence, frequent use) between 2019 and the previous year. Trends in each specific flavor type used from 2016 to 2019 were examined separately, with the annual percentage change calculated using Joinpoint regression[14]; analyses were not conducted for flavor categories if any of the estimates were suppressed. Two-sided *P* values less than .05 were considered statistically significant. Because of the lack of adjustment for multiple comparisons, findings from analyses of differences for flavored e-cigarette use and across survey years have the potential for type I error.

Results

A total of 19 018 high school and middle school students participated in the 2019 NYTS (overall response rate: 66.3%; product of school [77.2%] and student [85.8%] participation rates) (**Table 1**). Of these, 9099 were female (47.7%) and 9352 were non-Hispanic white (54.9%). The distribution of participants was similar across grades, ranging from 2306 (12.9%) in 12th grade to 3024 (14.6%) in seventh grade. Participants who indicated that they were ungraded, were in another grade, or who did not respond to that question (n = 84, 0.4%) were excluded from analyses stratified by school type. Among the 10 097 high school students who participated in the survey, the mean (SD) age was 16.1 (3.0) years and 47.5% were female; among the 8837 middle school students who participated, the mean (SD) age was 12.7 (2.8) years and 48.7% were female.

In 2019, an estimated 27.5% (95% CI, 25.3%-29.7%) of high school students reported current use of e-cigarettes and an estimated 5.8% (95% CI, 4.6%-7.3%) reported smoking cigarettes (**Table 2**). In total, an estimated 31.2% (95% CI, 29.1%-33.5%) of high school students reported current use of any

Table 1. Sociodemographic Characteristics of High School and Middle School Students, 2019

Characteristic[a]	High School Students		Middle School Students	
	Unweighted, No.	Weighted % (95% CI)	Unweighted, No.	Weighted % (95% CI)
Sex				
Female	4766	47.5 (44.8-50.1)	4310	48.7 (47.5-49.9)
Male	5291	52.5 (49.9-55.2)	4471	51.3 (50.1-52.5)
Race and ethnicity				
Non-Hispanic white	4698	52.9 (47.1-58.6)	3818	50.9 (46.0-55.7)
Non-Hispanic black	1189	12.6 (9.3-16.8)	1092	12.6 (9.9-15.9)
Hispanic	2897	24.0 (20.3-28.2)	2639	26.1 (22.7-29.7)
Non-Hispanic other race	1198	10.5 (8.6-12.8)	976	10.4 (9.1-11.9)
Grade				
6th			2944	33.2 (31.1-35.4)
7th			3024	33.3 (31.6-35.1)
8th			2869	33.5 (31.7-35.2)
9th	2790	27.4 (25.8-29.0)		
10th	2499	25.7 (24.4-27.0)		
11th	2502	23.9 (22.9-24.8)		
12th	2306	23.1 (21.8-24.4)		

[a] There were 116 respondents (0.54%) missing data on sex, 446 respondents (2.3%) missing data on race and ethnicity, and 84 respondents (0.39%) missing data on grade level.

Table 2. Estimated Percentage of Tobacco Use in the Past 30 Days, by Product and School, 2019

Tobacco Product	High School Students		Middle School Students	
	Unweighted, No.	Weighted % (95% CI)	Unweighted, No.	Weighted % (95% CI)
e-Cigarettes[a]	2709	27.5 (25.3-29.7)	902	10.5 (9.4-11.8)
Cigarettes[b]	549	5.8 (4.6-7.3)	190	2.3 (1.8-2.9)
Any tobacco product[c]	3091	31.2 (29.1-33.5)	1085	12.5 (11.2-13.9)

[a] Past 30-day use of e-cigarettes was determined by asking, "During the past 30 days, on how many days did you use e-cigarettes?" Those who reported using e-cigarettes on 1 or more days of the past 30 days were considered current (past 30-day) users. There were 96 respondents (0.51%) missing data on past 30-day e-cigarette use.

[b] Past 30-day use of cigarettes was determined by asking, "During the past 30 days, on how many days did you smoke cigarettes?" Those who reported smoking cigarettes on 1 or more days of the past 30 days were considered current (past 30-day) users. There were 37 (0.20%) missing data on past 30-day cigarette smoking.

[c] Any tobacco product use was defined as use of any tobacco product (e-cigarettes, cigarettes, cigars, smokeless tobacco, hookahs, pipe tobacco, dissolvables, snus, and/or bidis) on 1 or more days in the past 30 days. There were 13 (0.10%) respondents missing data on past 30-day any tobacco use.

tobacco product. Among middle school students, an estimated 10.5% (95% CI, 9.4%-11.8%) reported current e-cigarette use and 2.3% (95% CI, 1.8%-2.9%) reported current cigarette smoking. In total, an estimated 12.5% (95% CI, 11.2%-13.9%) of middle school students reported current use of any tobacco product. Data on current e-cigarette, cigarette, and any tobacco use from 2016 to 2018 can be found in eTable 1 in the Supplement.

Among current e-cigarette users, an estimated 34.2% (95% CI, 31.2%-37.3%) of high school students and 18.0% (95% CI, 15.2%-21.2%) of middle school students reported using e-cigarettes on 20 or more days in the past 30 days (Table 3). An estimated 21.4% (95% CI, 19.0%-24.0%) of current e-cigarette users in high school and 8.8% (95% CI, 6.9%-11.2%) of users in middle school reported daily e-cigarette use (data on 2018 frequency of e-cigarette use can be found in eTable 2 in the Supplement). An estimated 63.6% (95% CI, 59.3%-67.8%) of high school students and 65.4% (95% CI, 60.6%-69.9%) of middle school students reported exclusive use of e-cigarettes. Among current e-cigarette users, an estimated 13.8% (95% CI, 12.0%-15.9%) of high school users and 16.8% (95% CI, 13.6%-20.7%) of middle school users reported not having a usual brand of e-cigarettes, and an estimated 59.1% (95% CI, 54.8%-63.2%) of high school users and 54.1% (95% CI, 49.1%-59.0%) of middle school users reported JUUL as their usual e-cigarette brand.

Among high school students, an estimated 72.2% (95% CI, 69.1%-75.1%) of current exclusive e-cigarette users reported current use of flavored e-cigarettes. Among middle school students, an estimated 59.2% (95% CI, 54.8%-63.4%) of current exclusive e-cigarette users reported current use of flavored e-cigarettes. The most frequently reported flavor categories were fruit (high school: 66.1% [95% CI, 62.4%-69.5%]; middle school: 67.7% [95% CI, 62.6%-72.5%]), menthol or mint flavor (high school: 57.3% [95% CI, 53.3%-61.3%]; middle school: 31.1% [95% CI, 25.6%-37.2%]), and candy, desserts, or other sweets (high school: 34.9% [95% CI, 31.3%-38.7%], middle school: 38.3% [95% CI, 32.6%-44.2%]). Data on flavored e-cigarette use in 2018 can be found in eTable 2 in the Supplement. Given the large proportion of JUUL use among youth, differences in the use of flavored e-cigarettes and specific flavor types used were examined among JUUL users and compared with those who reported use of another brand or indicated no usual brand

Table 3. Frequency of Use, Flavored Use, Flavor Types, and Usual Brand Among e-Cigarette Users, 2019

	High School Students		Middle School Students	
	Unweighted, No.	% (95% CI)	Unweighted, No.	% (95% CI)
Among Past 30-d e-Cigarette Users[a]				
Frequency of e-cigarette use in the past 30 d				
<20 d	1792	65.8 (62.7-68.8)	749	82.0 (78.8-84.8)
≥20 d	917	34.2 (31.2-37.3)	153	18.0 (15.2-21.2)
Daily e-cigarette use[b]	564	21.4 (19.0-24.0)	80	8.8 (6.9-11.2)
Exclusive e-cigarette use	1740	63.6 (59.3-67.8)	612	65.4 (60.6-69.9)
Usual brand[c]				
No usual brand	383	13.8 (12.0-15.9)	138	16.8 (13.6-20.7)
JUUL	1520	59.1 (54.8-63.2)	496	54.1 (49.1-59.0)
SMOK	205	7.8 (6.0-10.1)	40	4.1 (2.7-6.1)
Suorin	110	3.1 (2.1-4.5)	NA[d]	NA[d]
blu	77	2.6 (1.9-3.6)	32	4.0 (2.4-6.6)
Vuse	56	2.1 (1.4-3.1)	43	4.6 (3.0-7.0)
NJOY	32	1.2 (0.7-2.1)	NA[d]	NA[d]
Logic	23	0.8 (0.5-1.4)	NA[d]	NA[d]
MarkTen	20	0.8 (0.4-1.4)	NA[d]	NA[d]
Some other brand	256	8.4 (7.2-10.5)	90	10.5 (8.1-13.5)
Among past 30-d Exclusive e-Cigarette Users[e]				
Flavored e-cigarette use[f]				
Flavored	1257	72.2 (69.1-75.1)	376	59.2 (54.8-63.4)
Unflavored	440	25.4 (22.5-28.5)	216	38.1 (33.7-42.8)
Unknown	43	2.5 (1.7-3.6)	20	2.7 (1.6-4.5)
Flavor types reported used[g]				
Fruit	832	66.1 (62.4-69.5)	248	67.7 (62.6-72.5)
Menthol or mint	703	57.3 (53.3-61.3)	132	31.1 (25.6-37.2)
Candy, desserts, or other sweets	430	34.9 (31.3-38.7)	139	38.3 (32.6-44.2)
Chocolate	26	1.8 (1.2-2.9)	30	8.1 (5.1-12.7)
Alcoholic drink	28	2.3 (1.5-3.5)	14	4.4 (2.5-7.7)
Clove/spice	NA[d]	NA[d]	NA[d]	NA[d]
Other flavor not listed	112	8.8 (7.2-10.7)	40	9.4 (6.7-13.0)

Abbreviation: NA, not available.

[a] Past 30-day use of e-cigarettes was determined by asking, "During the past 30 days, on how many days did you use e-cigarettes?" Current use was defined as use on 1 or more days in the past 30 days.

[b] Daily e-cigarette use is defined as reported use on all 30 of the past 30 days.

[c] For 2019, usual brand of e-cigarettes was determined by response to the question, "During the past 30 days, what brand of e-cigarettes did you usually use?" Participants could select from a list of options to designate their usual brand used including I did not use a usual brand, blu, JUUL, Logic, MarkTen, NJOY, Vuse, or some other brand not listed here (specify). Those who selected "some other brand not listed here" could specify with a write-in response. The write-in responses were examined (n = 725) and recoded. Only recoded responses for SMOK and Suorin were included in this report. There were 38 students (1%) missing brand data.

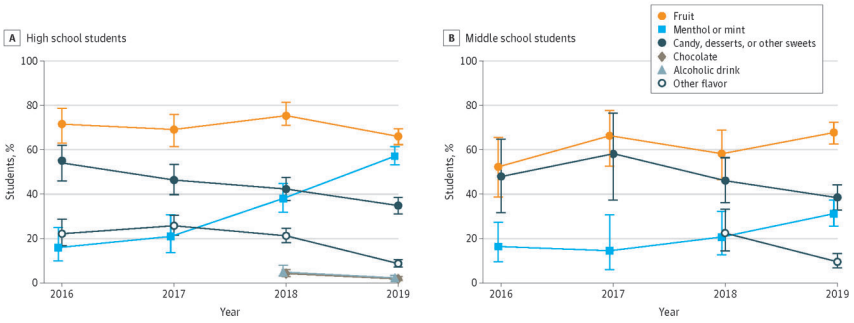
[d] Data are statistically unreliable due to unweighted denominator less than 50 or relative standard error greater than 30%.

[e] Exclusive e-cigarette use was defined as use of only e-cigarettes in the past 30 days.

[f] Flavored e-cigarette use was determined by the response to the question, "Which of the following tobacco products that you used in the past 30 days were flavored to taste like menthol (mint), alcohol (wine, cognac), candy, fruit, chocolate, or any other flavors? (Select one or more)." Participants could select from a list of options to designate the flavored tobacco product they used in the past 30 days including cigars, cigarillos, or little cigars; chewing tobacco, snuff, or dip; e-cigarettes; tobacco in a hookah or waterpipe; pipe filled with tobacco (not waterpipe); snus; dissolvable tobacco products; bidis; roll-your-own cigarettes; or I did not use any flavored tobacco products in the past 30 days. Among those who reported past 30-day e-cigarette use, those who selected e-cigarettes were defined as current flavored e-cigarette users. Respondents who were past 30-day e-cigarette users and did not select e-cigarettes or selected I did not use any flavored tobacco products in the past 30 days were classified as unflavored. Respondents missing a response were classified as unknown.

[g] Among those who used flavored e-cigarettes in the past 30 days, flavor type was determined by responses to the question, "What flavors of tobacco products have you used in the past 30 days? (Select one or more)." Participants could select from a list of options to designate the flavor they had used including menthol or mint; clove or spice; fruit; chocolate; alcoholic drink (such as wine, cognac, margarita, or other cocktails); candy, desserts, or other sweets; or some other flavor not listed here (specify). Respondents could select 1 or more of the 7 prespecified flavors. Those who indicated some other flavor not listed here could specify with a write-in response; the qualitative assessment of these responses (n = 358) is not included in this report. Those who did not select any of the prespecified flavors were set to missing.

Figure. Flavor Types Reported Among Current Exclusive e-Cigarette Users Who Reported Flavored e-Cigarette Use, 2016-2019



The error bars indicate 95% CIs. Data are statistically unreliable due to unweighted denominator less than 50 or relative standard error greater than 30%. Among high school students, estimates of chocolate (2016-2017), alcohol (2016-2018), and clove/spice (2016-2019) were suppressed. Among middle school students, estimates of chocolate (2016-2018), alcohol (2016-2018), clove/spice (2016-2019), and other (2016-2017) were suppressed.

Among past 30-day flavored e-cigarette users, flavor type was determined by responses to the question, "What flavors of tobacco products have you used in the past 30 days? (Select one or more)." Participants could select from a list of options to designate the flavor they had used including menthol or mint; clove or spice; fruit; chocolate; alcoholic drink (such as wine, cognac, margarita, or other cocktails); candy, desserts, or other sweets; or some other flavor not listed here (specify). Respondents could select 1 or more of the 7 prespecified flavors. Those who indicated "some other flavor not listed here" could specify with a write-in response; the qualitative assessment of these responses (n = 358) is not included in this report. Those who did not select any of the prespecified flavors were set to missing.

Past 30-day use of e-cigarettes was determined by asking, "During the past 30 days, on how many days did you use e-cigarettes?" Current use was defined use on 1 or more days in the past 30 days.

Exclusive electronic cigarette use was defined as use of only e-cigarettes in the past 30 days.

Flavored e-cigarette use was determined by the response to the question, "Which of the following tobacco products that you used in the past 30 days were flavored to taste like menthol (mint), alcohol (wine, cognac), candy, fruit, chocolate, or any other flavors? (Select one or more)." Participants could select from a list of options to designate the flavored tobacco product they used in the past 30 days including cigars, cigarillos, or little cigars; chewing tobacco, snuff, or dip; e-cigarettes; tobacco in a hookah or waterpipe; pipe filled with tobacco (not waterpipe); snus; dissolvable tobacco products; bidis; roll-your-own cigarettes; or I did not use any flavored tobacco products in the past 30 days. Among those who reported past 30-day e-cigarette use, those who selected e-cigarettes were defined as current flavored e-cigarette users. Respondents who were past 30-day e-cigarette users and did not select e-cigarettes or selected I did not use any flavored tobacco products in the past 30 days were classified as unflavored. Respondents missing a response were classified as unknown.

Between 2018 and 2019, the National Youth Tobacco Survey changed from paper and pencil to electronic administration. Please see the Methods section for a complete description of changes. Although direct comparisons between 2018 and 2019 are not conducted, trends using multiple years of data are not as affected by the mode change.

(eTable 3 in the Supplement). In sensitivity analyses recoding the 358 "other" flavor write-in responses, small increases in reported use of fruit and candy, desserts, and other sweet flavors were observed. However, the overall patterns did not change and the percentage of current users of fruit- and menthol- or mint-flavored e-cigarettes remained similar.

Sample sizes (overall response rates) for 2016, 2017, and 2018, were 20 675 (71.2%), 17 872 (68.1%), and 20 189 (68.2%), respectively.[11] From 2016 to 2019, there were significant changes in the reported flavor types used by current exclusive e-cigarette users in high school (**Figure**, A; eTable 4 in the Supplement). Current use of menthol- or mint-flavored e-cigarettes increased among current exclusive e-cigarette users in high school from 16.0% (95% CI, 9.8%-25.0%) in 2016 to 57.3% (95% CI, 53.3%-61.3%) in 2019 (annual percentage change = 55.2% [95% CI, 37.4%-75.2%]; $P = .004$). Current use of candy-, dessert-, and other sweet-flavored e-cigarettes decreased from 54.1% (95% CI, 46.0%-62.0%) in 2016 to 34.9% (95% CI, 31.3%-38.7%) in 2019 (annual percentage change = −13.3% [95% CI, −18.4% to −8.0%]; $P = .009$), and use of fruit-flavored e-cigarettes did not significantly change ($P > .05$). No significant trends in the use of menthol- or mint-, candy-, or fruit-flavored e-cigarettes were observed among current exclusive e-cigarette users in middle school (Figure, B; eTable 4 in the Supplement).

Discussion

In 2019, the prevalence of self-reported current e-cigarette use was high among US high school and middle school students, while self-reported current cigarette smoking among high school students has declined to historic lows.[2] With the assumption that the prevalence estimates from this survey are nationally representative and could be used to project to national population totals for US high school and middle school students, the data would suggest that in 2019, an estimated 4.1 million high school students and 1.2 million middle school students currently use e-cigarettes, an estimated 1.6 million students reported frequent use of e-cigarettes, an estimated 970 000 students use e-cigarettes daily, and an estimated

2.4 million exclusive e-cigarette users use flavored e-cigarettes. The data also would suggest that among these exclusive e-cigarette users, an estimated 1.6 million high school and middle school students use fruit-flavored e-cigarettes, an estimated 1.2 million use menthol- or mint-flavored e-cigarettes, and an estimated 830 000 use candy-, dessert-, or other sweet-flavored e-cigarettes.

The results of this survey are particularly concerning given relatively high exposure to nicotine through the use of nicotine salt-based e-cigarette products such as JUUL,[15] which was the most commonly reported brand among youth using e-cigarettes in 2019. Nicotine salts allow particularly high levels of nicotine to be inhaled more easily, with less irritation than the free-base nicotine that has traditionally been used in tobacco products including e-cigarettes.[6] For young people, this is of particular concern because it could promote the development of nicotine dependence, making it easier to initiate and proceed to regular e-cigarette use or transition to cigarette or other combustible tobacco product use.[6] Furthermore, the aerosol that users inhale and exhale from e-cigarettes can potentially expose themselves and bystanders to other harmful substances including heavy metals, volatile organic compounds, and ultrafine particles that can be inhaled deeply into the lungs.[5,6]

This is, to our knowledge, the first national study to show the increasing popularity of menthol- and mint-flavored e-cigarettes among youth. In this study, the 2016 data showed that menthol or mint flavors were selected much less frequently than fruit- or candy-flavored e-cigarettes by high school students. This is consistent with findings from the Population Assessment of Tobacco and Health Study (2014-2015, wave 2), which found that mint- and menthol-flavored e-cigarettes were the fourth most popular flavor among youth aged 12 to 17 years.[16] Additionally, another study conducted in 2014-2015 found that among youth aged 12 to 17 years, mint/menthol (24%) was ranked the fourth most popular flavor, behind fruit (76%), candy/other sweets (57%), and other (46%).[17] However, the current study found a significant increase in reported use of menthol- or mint-flavored e-cigarettes among high school students between 2016 and 2019 to levels near that of fruit-flavored e-cigarettes.

In November 2018, the Food and Drug Administration announced several new steps to protect youth, including restricting sales of flavored e-cigarettes (other than tobacco, menthol, mint, or nonflavored) to physical locations with age restrictions or online with heightened age-verification procedures.[18] After that announcement, certain manufacturers announced they would stop selling flavored e-cigarettes, except for mint/menthol.[19,20] However, after the announcement, stores could sell any remaining stock of flavored products from these manufacturers; moreover, mint-, menthol-, and tobacco-flavored products continued to be available in retail stores.[20] Additionally, flavored pods, in particular, were still available online[20] and youth could use compatible nonbranded flavored pods in their devices, consistent with recent reports showing increases in sales of these compatible pods in fruit flavors.[21] While data collection for the 2019 NYTS occurred after the announcement by certain manufacturers, supplemental analyses from the 2019 survey showed that most youth users were using flavored e-cigarettes in the spring of 2019, most of whom reported using mint or menthol flavors. The shift in the availability of e-cigarette flavors, due in part to the removal of flavors other than mint or menthol by certain manufacturers, may partially explain the increase in use of menthol- or mint-flavored e-cigarettes over time in this study. However, use of fruit-flavored e-cigarettes remains high among e-cigarette users in both high school and middle school.

Usual brand of e-cigarette used was first assessed in the 2019 survey. Most youth who were current e-cigarette users reported JUUL as their usual e-cigarette brand in 2019; the next most frequent response was "no usual brand." This mirrors trends in retail sales data showing that JUUL has held the majority of the market share of US e-cigarette sales since December 2017.[4,22] In the past year, public awareness of JUUL use by youth has expanded due to coverage in the popular media[23-25] and public health messaging[6] focused on the risks of e-cigarette use among youth. Estimates for JUUL use from the 2019 survey are based on a measure asking about usual brand used during the past 30 days. This question may underestimate use if casual users do not identify JUUL as their usual brand. Conversely, as the term "Juuling" has become synonymous for "vaping" for some youth,[26] youth users may believe they are using a JUUL device when they are actually using a device or pod that mimics this brand. Furthermore, youth users may incorrectly identify using JUUL due to brand recognition alone, which could result in an overestimation of use.[27]

Limitations

This study has several limitations. First, several improvements were made to the NYTS in 2019, including switching from a paper-and-pencil to an electronic survey administration, adding skip patterns and unbranded example product images, and updating brand examples to reflect the current tobacco marketplace. Although brand examples in the survey are added or removed as needed to account for changes in the current tobacco product market share, the rapid increase in JUUL use before 2019[4,20] and subsequent inclusion as a brand example in 2019 may limit the comparability of e-cigarette and overall tobacco product use estimates with previous years. As the exact magnitude of the effect of these survey improvements in 2019 cannot be fully quantified, direct statistical comparisons of tobacco product use estimates between 2019 and previous years were not conducted. However, trend analyses of flavor types used during 2016 to 2019 were conducted; this analysis uses more data points and is thus less dependent on methods changes during a single year.

Second, for the survey measure assessing flavor types used, response options allowed respondents to check all that apply, rather than a forced-choice option, which may yield different results.

Third, information on flavor types used for individual tobacco products cannot be determined for youth who report using multiple flavored tobacco products. Therefore, data on flavor types used were only reported among current exclusive e-cigarette users for the current analysis, which

account for approximately two-thirds of all current e-cigarette users.

Fourth, the response rate was 66.3% and there may be differences in tobacco use between those who participated in the survey and those who did not.

Fifth, data were collected from youth who attended public or private school; therefore, the findings may not be generalizable to youth who are homeschooled, have dropped out of school, or are in detention centers. However, data from the Current Population Survey indicate that nearly 97% of US youth aged 10 to 17 years were enrolled in a traditional school in 2017.[28]

Sixth, the underlying assumptions used for the population estimates should be considered in interpreting the data for projections to national estimates of e-cigarette use.

Conclusions

In 2019, the prevalence of self-reported e-cigarette use was high among high school students and middle school students, with many current e-cigarette users reporting frequent use and most of the exclusive e-cigarette users reporting use of flavored e-cigarettes.

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REFERENCES

1. US Department of Health and Human Services. *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. Rockville, MD: US Dept of Health and Human Services, Public Health Service, Office of the Surgeon General;2012.

2. Gentzke AS, Creamer M, Cullen KA, et al. Vital signs: tobacco product use among middle and high school students—United States, 2011–2018. *MMWR Morb Mortal Wkly Rep*. 2019;68(6):157-164. doi:10.15585/mmwr.mm6806e1

3. Cullen KA, Ambrose BK, Gentzke AS, Apelberg BJ, Jamal A, King BA. Notes from the field: use of electronic cigarettes and any tobacco product among middle and high school students—United States, 2011-2018. *MMWR Morb Mortal Wkly Rep*. 2018;67(45):1276-1277. doi:10.15585/mmwr.mm6745a5

4. King BA, Gammon DG, Marynak KL, Rogers T. Electronic cigarette sales in the United States, 2013-2017. *JAMA*. 2018;320(13):1379-1380. doi:10.1001/jama.2018.10488

5. US Department of Health and Human Services. *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta, GA: US Dept of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2016.

6. US Department of Health and Human Services. Surgeon General's advisory on e-cigarette use among youth. https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf. Accessed September 10, 2019.

7. Wang TW, Gentzke A, Sharapova S, Cullen KA, Ambrose BK, Jamal A. Tobacco product use among middle and high school students—United States, 2011-2017. *MMWR Morb Mortal Wkly Rep*. 2018;67(22):629-633. doi:10.15585/mmwr.mm6722a3

8. Statement from FDA Commissioner Scott Gottlieb, MD, on new steps to address epidemic of youth e-cigarette use [press release]. Silver Spring, MD: US Food and Drug Administration; September 11, 2018. https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use. Accessed September 10, 2019.

9. Food and Drug Administration. FDA's Youth Tobacco Prevention Plan. https://www.fda.gov/tobacco-products/youth-and-tobacco/fdas-youth-tobacco-prevention-plan. Updated June 19, 2019. Accessed September 10, 2019.

10. Public Health Law Center at Mitchell Hamline School of Law. US e-cigarette regulations: 50 state review (2019). https://www.publichealthlawcenter.org/resources/us-e-cigarette-regulations-50-state-review. Updated June 15, 2019. Accessed September 6, 2019.

11. Centers for Disease Control and Prevention. National Youth Tobacco Survey (NYTS). https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/index.htm. Updated February 28, 2019. Accessed September 10, 2019.

12. Hu SS, Gentzke A, Jamal A, Homa DM, Neff LJ. Feasibility of conducting an electronic version of the National Youth Tobacco Survey (NYTS), 2018. Paper presented at: 2019 National Conference on Tobacco or Health; August 27, 2019; Minneapolis, MN.

13. Nielsen Scantrack. https://www.nielsen.com/pk/en/solutions/measurement/retail-measurements/. Accessed October 22, 2019.

14. National Cancer Institute. Surveillance Research Program: Joinpoint. https://surveillance.cancer.gov/help/joinpoint. Accessed November 9, 2018.

15. Goniewicz ML, Boykan R, Messina CR, Eliscu A, Tolentino J. High exposure to nicotine among adolescents who use Juul and other vape pod systems ("pods") [published September 7, 2018]. *Tob Control*. doi:10.1136/tobaccocontrol-2018-054565

16. Schneller LM, Bansal-Travers M, Goniewicz ML, McIntosh S, Ossip D, O'Connor RJ. Use of flavored electronic cigarette refill liquids among adults and youth in the US: results from wave 2 of the Population Assessment of Tobacco and Health Study (2014-2015). *PLoS One*. 2018;13(8):e0202744. doi:10.1371/journal.pone.0202744

17. Harrell MB, Weaver SR, Loukas A, et al. Flavored e-cigarette use: characterizing youth, young adult, and adult users. *Prev Med Rep*. 2016;5:33-40. doi:10.1016/j.pmedr.2016.11.001

18. Statement from FDA Commissioner Scott Gottlieb, MD, on proposed new steps to protect youth by preventing access to flavored tobacco products and banning menthol in cigarettes [press release]. Silver Spring, MD: US Food and Drug Administration; November 15, 2018. https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access. Accessed September 10, 2019.

19. Giammona C. Altria pulls e-cig flavors after FDA cracks down on youth usage. Bloomberg. https://www.bloomberg.com/news/articles/2018-10-25/altria-pulls-e-cig-flavors-after-fda-cracks-

down-on-youth-usage. Published October 25, 2018. Accessed September 10, 2019.

20. JUUL labs action plan: message from Kevin Burns, CEO, JUUL Labs [press release]. San Francisco, CA: JUUL Labs; November 13, 2018. https://newsroom.juul.com/2018/11/13/juul-labs-action-plan/. Accessed September 10, 2019.

21. Kaplan S. "Juul-alikes" are filling shelves with sweet, teen-friendly nicotine flavors. *New York Times*. https://www.nytimes.com/2019/08/13/health/juul-flavors-nicotine.html. Published August 13, 2019. Accessed September 10, 2019.

22. Craver R. JUUL ends 2018 with 76 percent market share. *Winston-Salem Journal*. https://www.journalnow.com/business/juul-ends-with-percent-market-share/article_6f50f427-19ec-50be-8b0c-d3df18d08759.html. Published January 8, 2019. Accessed September 10, 2019.

23. Ducharme J. Teens are "juuling" at school: here's what that means. *Time*. https://time.com/5211536/what-is-juuling/. Updated March 27, 2018. Accessed September 10, 2019.

24. Hoffman J. The price of cool: a teenager, a Juul and nicotine addiction. *New York Times*. https://www.nytimes.com/2018/11/16/health/vaping-juul-teens-addiction-nicotine.html. Published November 16, 2018. Accessed September 10, 2019.

25. Balingit M. In the "Juul room": e-cigarettes spawn a form of teen addiction that worries doctors, parents and schools. *Washington Post*. https://www.washingtonpost.com/local/education/helpless-to-the-draw-of-nicotine-doctors-parents-and-schools-grapple-with-teens-addicted-to-e-cigarettes/2019/07/25/e1e8ac9c-830a-11e9-933d-7501070ee669_story.html. Published July 26, 2019. Accessed September 10, 2019.

26. JUUL Labs files complaint with the United States International Trade Commission [press release]. San Francisco, CA: JUUL Labs; October 4, 2018. https://newsroom.juul.com/2018/10/04/juul-labs-files-complaint-with-the-united-states-international-trade-commission/. Accessed September 10, 2019.

27. Willett JG, Bennett M, Hair EC, et al. Recognition, use and perceptions of JUUL among youth and young adults. *Tob Control*. 2019;28(1):115-116.

28. US Census Bureau. School enrollment in the United States: October 2017—detailed tables. https://www.census.gov/data/tables/2017/demo/school-enrollment/2017-cps.html. Published December 11, 2018. Accessed September 10, 2019.

[Whereupon, at 12:22 p.m., the hearing was adjourned.]

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